HAWAII BOARD OF PHARMACY
Professional and Vocational Licensing Division
Department of Commerce and Consumer Affairs
State of Hawaii

AGENDA

Date: September 24, 2026

Time: 9:00 a.m.

In-Person Meeting Location:
Queen Liliuokalani Conference Room
HRH King Kalakaua Building, 1st Floor
335 Merchant Street
Honolulu, Hawaii 96813

Virtual Participation:
Videoconference Meeting – Zoom Meeting (use link below)
https://dcca-hawaii-gov.zoom.us/j/82214723782?pwd=rFHsb9oo5RJJeEcifcXgAmbi90E8go.1

Phone: (669) 900-6833

Meeting ID: 822 1472 3782

Passcode: 452898

Agenda: The agenda was posted to the State electronic calendar as required by Hawaii Revised Statutes ("HRS") section 92-7(b).

'ŌLELO TV:

Subject to the availability of 'Ōlelo personnel, members of the public may also view the meeting by televised live broadcast on 'Ōlelo TV.

If you wish to submit written testimony on any agenda item, please email your testimony to pharmacy@dcca.hawaii.gov or by hard copy mail to: Attn: Board of Pharmacy, P.O. Box 3469, Honolulu, HI 96801. We request submission of testimony at least 24 hours prior to the meeting to ensure that it can be distributed to the Board members. Testimony received after that time will still be distributed to the board, but may not reach members prior to the meeting

INTERNET ACCESS:

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Your microphone will be automatically muted. When the Chairperson asks for public testimony, you may click the Raise Hand button found on your Zoom screen to indicate that you wish to testify about that agenda item. The Chairperson will individually enable each testifier to unmute

their microphone. When recognized by the Chairperson, please unmute your microphone before speaking and mute your microphone after you finish speaking.

PHONE ACCESS:

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When the Chairperson asks for public testimony, you may indicate you want to testify by entering "*" and then "9" on your phone's keypad. After entering "*" and then "9", a voice prompt will let you know that the host of the meeting has been notified. When recognized by the Chairperson, you may unmute yourself by pressing "*" and then "6" on your phone. A voice prompt will let you know that you are unmuted. Once you are finished speaking, please enter "*" and then "6" again to mute yourself.

For both internet and phone access, when testifying, you will be asked to identify yourself and the organization, if any, that you represent. Each testifier will be limited to five minutes of testimony per agenda item.

If connection to the meeting is lost for more than 30 minutes, the meeting will be continued on a specified date and time. This information will be provided on the Board's website at https://cca.hawaii.gov/pvl/boards/pharmacy/meeting_schedule/

Instructions to attend State of Hawaii virtual board meetings may be found online at https://cca.hawaii.gov/pvl/files/2020/08/State-of-Hawaii-Virtual-Board-Attendee-Instructions.pdf

If you need an auxiliary aid/service or other accommodation due to a disability, contact the Hawaii Pharmacy Board at (808) 587-8852 as soon as possible, preferably by two business days prior to the scheduled meeting. Requests made as early as possible have a greater likelihood of being fulfilled. Upon request, this notice is available in alternate/accessible formats.

1. **Establish Quorum, Public Notice, Call to Order, HRS §92-3 Open Meetings**

2. **Approval of Minutes:**
   The Board may move into Executive Session in accordance with HRS §§92-4, 92-5(a)(1), and 92-5(a)(4) to consider and evaluate personal information relating to individuals applying for professional or vocational licenses cited in HRS §26-9 or both and to consult with the Board's attorney on questions and issues pertaining to the Board's powers, duties, privileges, immunities, and liabilities. The Board will vote in Open Session.

   A. July 23, 2026, Open Session Meeting Minutes

   B. July 23, 2026, Executive Session Meeting Minutes

3. **Chair's Report**

   A. Report on Board Member participation in the NABP Multistate Pharmacy Jurisprudence Examination (MPJE) State-Specific Review on September 16-18, 2026.

   B. Seventh Emergency Proclamation Relating to Pharmacist-Provided Vaccination Services (Sept. 8, 2026), temporarily allowing continued pharmacist administration of COVID-19 and influenza vaccines without 2026-2027 ACIP guidance

4. **New Business:**
   The Board may move into Executive Session in accordance with HRS §§92-4 and 92-5(a)(4) to consult with the Board's attorney on questions and issues pertaining to the Board's powers, duties, privileges, immunities, and liabilities. The Board will vote in Open Session.

   A. Costco Pharmacy's Request for Guidance on Installation and Operation of iLocalBox Fastlane Delivery Kiosks (Prescription Storage and Pickup Lockers)
      i. Board expectations for required security protocols and patient counseling procedures associated with the pharmacy locker operation;
      ii. Applicable documentation, application, and inspection requirements; and,
      iii. Whether the board's approval or an advisory opinion is required.

   B. East Hawaii Health Pharmacy's Request for Guidance on Installation and Operation of a Prescription Storage and Pickup Locker at Rural Health Clinic Locations
      i. Whether the clinics where the locker would be installed must obtain a pharmacy permit;
      ii. Applicable inspection, security, recordkeeping, and operational requirements;
      iii. Whether controlled substances are permitted to be stored and dispensed from such machine;
      iv. Personnel authorized to stock and replenish the locker; and
      v. Requirements related to quality assurance, audits, environmental monitoring, machine maintenance, and diversion-prevention protocols.

   C. Request for clarification on whether a Hawaii licensed pharmacist is allowed to establish and operate a non-dispensing pharmacy solely for providing pharmacist clinical services, and if so, what physical location or facility requirements would apply, including whether any of those requirements may be waived or modified for a non-dispensing practice.

   D. Request for clarification on whether an out-of-state centralized prescription drug order processing pharmacy that does not store or dispense medications is required to be licensed before operating services for patients in Hawaii.

   E. Request for clarification on whether the Board requires that non-compounding pharmacies comply with US Pharmacopeia (USP) 800, which provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients and the environment.

F. Eli Lily and Company's notice regarding the widespread unlawful manufacturing, compounding, advertising, prescribing, dispensing, and selling of retatrutide, an unapproved drug product, and request for the Board's action to help protect Hawaii consumers.

G. Information sharing regarding US Food and Drug Administration (FDA)'s letter related to the labeling of compounded glucagon-like peptide-1 (GLP-1) receptor agonist medications and the handling of multidose vials.

H. Information sharing regarding FDA's Drug Supply Chain Security Act (DSCSA) exemptions from certain requirements under Section 582 of the Food, Drug & Cosmetic Act for small business dispensers until November 27, 2027.
   i. Small dispensers are encouraged to complete assessment survey by September 22, 2026 accessible on FDA's website.

I. Information sharing regarding upcoming changes to the communication skills requirement for obtaining the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification.
   i. Beginning in November 2026, candidates who take the Test of English as a Foreign Language Internet-based Test (TOEFL iBT) may use MyBest scores.
   ii. Beginning on January 11, 2027, FPGEC candidates may use the Occupational English Test (OET) as an accepted assessment for communication skills.

5. **Old Business:**
The Board may move into Executive Session in accordance with HRS §§92-4 and 92-5(a)(4) to consult with the Board's attorney on questions and issues pertaining to the Board's powers, duties, privileges, immunities, and liabilities. The Board will vote in Open Session.

A. Amendments to the Hawaii Administrative Rule ("HAR") Title 16 Chapter 95

The Board will review and discuss proposed amendments to HAR Chapter 95, which governs the licensure and regulation of Pharmacists and Pharmacies.

The proposed amendments include revisions to the following sections: (a copy of the Rules is attached to the agenda)

Revised	
16-95-2	Definitions
16-95-14	Display of license or permit
16-95-21	Forms, documentation, and notification.
16-95-22	Application and requirements for pharmacist license by examination
16-95-23	Temporary License
16-95-26	Pharmacy permit
16-95-30	Wholesale prescription drug distributor license requirements
16-95-31	Miscellaneous permit
16-95-33	Education documentation for a pharmacist license
16-95-36	Experience verification for a pharmacist license by reciprocity or temporary pharmacist license
16-95-73	Restoration of forfeited license or permit
16-95-79	Supervision by a registered pharmacist

16-95-85	Scope of practice of a pharmacy intern
16-95-86	Scope of practice of a pharmacy technician

New Sections

16-95-131	Procedure to dispense a refill without practitioner authorization
16-95-132	Prescription Drug Label Information Accessibility
16-95-133	Drug Label Information Accessibility exemption
16-95-134	Remote Prescription Processing

6. **Applications for Licensure/Certification:**
The Board will move into Executive Session pursuant to HRS §§92-4, 92-5(a)(1), and 92-5(a)(4) to consider and evaluate personal information relating to individuals applying for professional or vocational licenses cited in HRS §26-9 or both and to consult with the Board's attorney on questions and issues pertaining to the Board's powers, duties, privileges, immunities, and liabilities. The Board will vote in Open Session.

A. Applications:

Pharmacy (PHY)

1) Clear Value Pharmacy LLC

Miscellaneous Permit (PMP)

2) Babcook Pharmacy LLC dba Premier Pharmacy

3) FarmaKeio Outsourcing LLC

4) Foundation Pharmacy LLC

5) KabaFusion, LLC

6) Pharmacist on Demand LLC dba Liberty Pharmacy

7) Jubilant DraxImage Inc dba Jubilant Radiopharma

B. Pharmacist in Charge Change

1) Melbourne Pharma, LLC (PMP-2306)

C. Ratification List of Approved Applications (attached to the agenda)

7. **Chapter 91, Adjudicatory Matters:**

A. In the Matter of the Miscellaneous Permit of F & F Pharmacies, Inc. doing business as Jungle Jim's Pharmacy, PHA 2026-26-L, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"

B. In the Matter of the Miscellaneous Permit of Optime Care Inc., PHA 2026-20-L Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"

8. **Next Meeting:**

Thursday, November 19, 2026
9:00 a.m.
Virtual Videoconference Meeting – Zoom Meeting and;
In-Person Meeting: Queen Liliuokalani Conference Room
HRH King Kalakaua Building
335 Merchant Street, Third Floor
Honolulu, HI 96813

9. **Adjournment**

BOARD OF PHARMACY
Professional and Vocational Licensing Division
Department of Commerce and Consumer Affairs State of Hawaii

RATIFICATION LIST: For the meeting held September 24, 2026
Date list was generated: 2026.09.17

License Number	Licensee
R-26713001	Shayla Jones
R-26717002	Hannah M Iwahiro
R-26720002	Nicole K Waikiki
R-26720003	Rylie E Adriano
R-26720004	Cathy B Emboltorio
R-26721002	Ayla C Boudreaux
R-26721003	Trevor R Blades
R-26721008	Cecilia Sze Ting Hoi
R-26721009	Carley Lanae Taylor Williams
R-26721010	Richel Marie Ped-Licos
R-26721011	Lucas S K Rowland
R-26722001	Makaila-Lei Kunishige
R-26722002	Lily M Glick
R-26722003	Daniella Sheena Dagdagan
R-26722004	Nicole L M Balidoy
R-26722005	Wendy A Ables
R-26722006	Sierra Mae S Reyes
R-26722007	Lauren Nhu-Nguyen Khen
R-26722008	HUIRYEON JO
R-26722009	Siedha M Palenapa
R-26723002	Naomi K Alquicira Martinez
R-26723001	Lacey J Manzano
R-26723003	Joshua L Cotterill
R-26809001	KYLE J ELLIS
R-26809002	JUSTIN IWAO TAO
R-26809003	LAVAR RAYMOND BRADLEY
R-26809004	CELIA OHRWALL
R-26809005	Robert I Morris
R-26810001	SECUNDINA SANA BUCANEG
R-26811001	ANGELA J JACKSON
R-26811002	Alejandra N Maldonado

R-26811003	ANTONIO HERNANDEZ JR.
R-26811004	Liana N Boarts
R-26811005	JENNY ROSE VILLAR CASTEL
R-26812001	LARA MAE L COLLADO
R-26813001	Manal Suleiman
R-26813002	Amber D E McElroy
R-26813003	Zachary M Munchrath
R-26813005	Aina M F H Smith
R-26813009	Bernadette E Gochu
R-26813010	EMMA SOFIA QUIROZ
R-26813011	Abigail E Gochu
R-26814001	SUSAN ESTRELLA GUERRERO
R-26814002	John Carlo D Doronio
R-26814004	Randi L Jandreau
R-26814005	MEGAN JENNIFER MCCALL
R-26819001	Samantha Grace K Daniels
R-26819003	ALINA NGUYEN
R-26819004	MONICA NICOL RAMIREZ
R-26825002	LAUREA JENA PANGILINAN BRIOSOS
R-26825003	LASHAUNDRIA M ALLEN
R-26825004	MICHELLE-NICOLE EHU-EHU AMERO
R-26825005	KOLBY MACE KANEKO
R-26825006	MATTHEW EASTER
R-26825007	EDYTON F TUMBAGA JR
R-26825009	TERRYSA HIROMI UYENO
R-26825010	PRIYA JOY MARIE ZAPANTA
R-26825011	REINA RUMI MATSUI
R-26825012	KIMBERLY YAEKO SABATI
R-26826001	LEIAKAWAI S.K. TAVARES-TURALDE
R-26826002	JAMES A MILLER
R-26826003	Tammy Makanalani Plascensia-Walker
R-26826004	Serina D Carter
R-26826005	Lisa Ballo
R-26826006	Heidi N Hublein
R-26826007	Kelly J Knutson
R-26826008	Chelsea Brown Ramirez
R-26826009	Adriana A Terrazas
R-26826010	Tess Hotchkiss
R-26826011	Drake A Herzog

R-26826012	Christopher S Moore
R-26826013	Jennifer L Bisarra
R-26826014	Victoria Lynn J Nilo
R-26826015	Ceili A E Blessley
R-26826016	Kristen C A Lostica
R-26826017	RAILYN D MAUGA
R-26827001	KACIE K VERANO-SMITH
R-26827002	VICTORIA KAU ILANI LEDERER
R-26827003	AKIRA CHRISTINA BLACKMON
R-26831001	KIANA K DAVIS
R-26831002	YUHONG HUANG
R-26831004	SUSAN DENISE HAGEDORN
R-26831005	Alexis B A Brown
R-26902001	SHANARA DARO MEJIAS
R-26902002	PRETTY JAMAICA GANITANO
R-26902003	ALAN K T LAU
R-26902004	LORIANN DENISE PIMENTEL
R-26903002	PAIGE ALEXANDRA LUMPKIN
R-26903003	JOHN PAUL BRUNET
R-26903004	Hailey A Pajimola
R-26904006	CARDIJAH ELIZABETH BETHEL
R-26904002	SANDRA LYNN VARNER
R-26904003	VALERI ANN GUZMAN
R-26904004	KEROLOS MANSOUR
R-26904005	VICTORIA ANNE VALENTINE
R-26904007	SABRINA JOU SONG DELMONICO
R-26904008	KELLY JO EAVES
R-26904009	KIDA KATESUDA SITHAVONG
R-26904010	FERNANDO VARGAS
R-26904011	SARAH LYNN PROPP
R-26909001	TASIA A HAYS
R-26909002	RACHELLE MAE BUTAC
R-26909003	ZOE KAULAWENA BUTAC
R-26909004	MIA MICHA C TABALDO
R-26909005	GAIL LEILANI COSTA
R-26910001	ROSELIND SU GONZALES
R-26910002	Mohammed H Elwir
R-26910003	JOSHUA BASUBAS ARMAS
R-26910004	CHRISTINE NAOMI KINA

R-26910005	MARIACAMILLE RAYMUNDO
R-26910006	EMMA L KEPO'O
R-26910007	LAURIE AKEMI LAU
R-26911001	BRENT AKIO NAKAMURA
R-26911002	CORI-ANN SHIGEKO DELOSO-ANCHETA
R-26911003	JEZELLE H O'ILI-VICENTE
R-26911004	KIANA K M MATTOS-FELICILDA
R-26911005	VALERIE CHRISLYN AINA-TEHANI BROWN
R-26911007	Kauhiwailiiliiokalani F Tam
R-26911008	LEZLIE-ANN DECORTE SILVA
R-26911009	SYDNEY KEALOHALANI CHUNG
R-26911010	BRITHANY U'ILANI MITSUKO ARIGA
R-26911011	CASEY LEE TAMAYO
R-26916001	TASIA J K KIPAPA
R-26916002	HALEY MEGAN YOUNG
R-26916003	MELANIE LEPEKA WOLF
R-26916004	ALONA JANE G PADAPAT
R-26916005	FAYE NINA QUINTANA ALEGADO
R-26916008	Jamison Ramon V Ramos
R-26715003	Dana R Walski
R-26723004	Lydia P Perdigao
R-26827004	Adrianne Macy Domingo Quiane
R-26827005	TAYLER LYNN RASMUSSEN
R-26827006	Megan Chock
R-26827007	MAPU MAI KE ALOHA PASCUAL AU
R-26827008	KACIE YUKIE KAMALANI MOKU
R-26827009	JADE-CHRISTEN MICHELS
R-26827012	Taylor R K Dunaway
R-26827010	ASHLEY RAE K MACKINAW
R-26827011	Kahanu Vista
R-26827013	Kayla Kazumi Cacho
R-26827014	IAN F SUTHERLAND
R-26827015	Brooklyn Reid
R-26827016	Czarinna Rae Fuentes
R-26827017	Allison Konrath
R-26827019	Aidan C Robertson
R-26827020	ANSON M OYAMA
R-26827021	LYNSIE ANN MACKINAW
R-26827022	Emylee Tennant

R-26827023	Merumo Ishimaru
R-26827024	Victoria Isabel Simone
R-26828001	TRISTAN J GUDOY
R-26828002	Harry Isim Broadbent
R-26828003	Kristen Galapon
R-26828004	KODY HAYASHI
R-26831003	Kyrina-Belle Yacas
R-26902005	Lei Angeline Ladd
R-26902007	SEANPAUL K KALEOPAA-TADAKI
R-26902008	Jaren Shimoko
R-26902009	KYLIE UMEKO KARIMOTO
R-26903005	BENJAMIN BARRUGA
R-26904001	Amaya Khrist Dagting
R-26911006	JAKE VINCENT ANGELO
R-26916006	MEGAN KATRINA HARY
PH-5255-0	Michael M Rho
PH-5256-0	Diana S Koro
PH-5257-0	NICOLE DZIUBA
PH-5258-0	Oanh Le Nguyen
PH-5259-0	CHRISTINE VI LE
PH-5260-0	Mandy Zheng
PH-5261-0	Joshua T Close
PH-5262-0	Jaccie T Hisashima
PH-5263-0	Katherine Vu
PH-5264-0	Lina Kishta
PH-5265-0	SKYE S M K PYO
PH-5266-0	Marvin Joubin Rositzki
PH-5267-0	Kirsten Maile Malapit
PH-5268-0	Sunwoo Oh
PH-5269-0	Tia M Leal
PH-5270-0	Danton Chase Juen Ming Nitta
PH-5271-0	Meagan S Funasaki
PH-5272-0	Vincent Tran
PH-5273-0	REBECCA NGUYEN LIEM
PH-5274-0	Ryan Davis
PH-5275-0	Victoria N Nguyen
PH-5276-0	Jaime M Leal Jr
PH-5277-0	BriAnna Lewis
PH-5278-0	Ashley Thuy Duong Dang

PH-5279-0	Danielle M Le
PH-5280-0	Amy Hoang
PH-5281-0	Iver O'Neal Vandiver II
PH-5282-0	Katie Daniels
PH-5283-0	Ronel Jordan R Quebral
PHY-986-0	University Clinical Education & Research Associates
PHY-987-0	Lucky Sails Drug, Inc.
PMP-2379-0	All Discount Pharmacy, LLC
PMP-2380-0	Geisinger Pharmacy LLC
PMP-2381-0	Geisinger Pharmacy LLC
PMP-2382-0	OptiMed Health Partners, LLC
PMP-2383-0	NERxD, LLC
PMP-2384-0	Pharmacy Enterprises of Texas, LLC
PMP-2385-0	TruPharmaRx, LLC
PMP-2386-0	Northern VA Compounders, PLLC
PMP-2387-0	Theragenix Pharmacy Inc.
PMP-2388-0	Strategic Pharmaceutical Solutions, Inc.
PMP-2389-0	Summit Health Pharmacy, LLC
PMP-2390-0	Synapse Health, Inc.
PMP-2391-0	Puramint LLC
PMP-2392-0	NI9 HEALTH GROUP LLC
PMP-2393-0	Costco Wholesale Corporation
PMP-2394-0	Tailstorm Health Inc
PMP-2395-0	MVP Pharmacy, LLC
PMP-2396-0	Senior Life Pharmacy GA, LLC
PMP-2397-0	AmerApex Rx, LLC
PMP-2398-0	US-RX DISTRIBUTION LLC
PMP-2399-0	Healix Infusion Therapy, LLC
PMP-2400-0	HYVACS, LLC
PMP-2401-0	Peninsula Pharmacies, Inc
PMP-2402-0	Optum Pharmacy 701, LLC
PMP-2403-0	Buderer Drug Company, Inc.
PMP-2404-0	MEDILINK RXCARE HAMMONTON, LLC
PMP-2405-0	STRIVE PHARMACY TAMPA LLC
PMP-2406-0	CASCADE SPECIALTY PHARMACY LLC
PMP-2407-0	EVEREST WAILLISVILLE PHARMACY LLC
PWD-208-0	Apria Healthcare LLC
PWD-209-0	ADAPTHEALTH WEST, LLC

DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
[REVISIONS PREVIOUSLY APPROVED BY BOARD IN RED]
[NOTES AND PROPOSED TEXT IN BLUE]

Amendment and Compilation of Chapter 16-95
Hawaii Administrative Rules

[DRAFT FOR JULY 23, 2026 MEETING]

1. Chapter 16-95, Hawaii Administrative Rules, entitled, "Pharmacists and Pharmacies", is amended and compiled to read as follows:

"HAWAII ADMINISTRATIVE RULES

TITLE 16

DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS

CHAPTER 95

PHARMACISTS AND PHARMACIES

Subchapter 1 General Provisions

§16-95-1 Objective; scope
§16-95-2 Definitions
§16-95-3 Repealed
§16-95-4 Repealed
§16-95-5 Repealed
§16-95-6 Repealed
§16-95-7 Repealed
§16-95-8 Repealed

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§16-95-9 Repealed
§16-95-10 Repealed
§16-95-11 Repealed
§16-95-12 Repealed
§16-95-13 Repealed
§16-95-14 Display of license or permit
§16-95-15 Repealed
§16-95-16 Repealed
§16-95-17 Repealed
§16-95-18 License or permit required
§16-95-19 License or permit nontransferable

Subchapter 2 Applications

§16-95-21 Forms, documentation, and notification
§16-95-22 Application and requirements for pharmacist license by examination
§16-95-22.5 Application and requirements for pharmacist license by reciprocity
§16-95-23 Temporary license
§16-95-24 Pharmacy intern permit
§16-95-25 Repealed
§16-95-26 Pharmacy permit
§16-95-27 Repealed
§16-95-28 Repealed
§16-95-29 Repealed
§16-95-30 Wholesale prescription drug distributor license requirements
§16-95-31 Miscellaneous permit
§16-95-32 Criminal conviction
§16-95-32.2 Denial or rejection of application

Subchapter 3 Education and Experience Documentation

§16-95-33 Education documentation for a pharmacist license
§16-95-33.2 Education documentation for a pharmacy intern permit

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§16-95-34 Experience verification for a pharmacist by examination
§16-95-35 Repealed
§16-95-36 Experience verification for a pharmacist license by reciprocity or temporary pharmacist license

Subchapter 4 Repealed

§16-95-39 Repealed
§16-95-40 Repealed
§16-95-41 Repealed
§16-95-42 Repealed
§16-95-43 Repealed

Subchapter 5 Repealed

§16-95-44 Repealed
§16-95-45 Repealed
§16-95-46 Repealed
§16-95-47 Repealed
§16-95-48 Repealed
§16-95-49 Repealed
§16-95-50 Repealed

Subchapter 6 Repealed

§16-95-51 Repealed
§16-95-52 Repealed
§16-95-53 Repealed
§16-95-54 Repealed

Subchapter 7 Repealed

§16-95-55 Repealed
§16-95-56 Repealed
§16-95-57 Repealed
§16-95-58 Repealed

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§16-95-59 Repealed
§16-95-60 Repealed
§16-95-61 Repealed
§16-95-62 Repealed
§16-95-63 Repealed
§16-95-64 Repealed

Subchapter 8 Repealed

§16-95-65 Repealed

Subchapter 9 Renewal

§16-95-70 Repealed
§16-95-71 Date for filing
§16-95-72 Automatic forfeiture for failing to renew
§16-95-73 Restoration of forfeited license or permit
§16-95-74 Board may refuse to renew or restore a license or permit

Subchapter 10 Scope of Practice

§16-95-79 Supervision by a registered pharmacist
§16-95-80 Physical presence of a registered pharmacist
§16-95-81 Emergency kits
§16-95-82 Valid prescriptions
§16-95-83 Substitution; drug product selection
§16-95-84 Transfer of prescriptions
§16-95-85 Scope of practice of a pharmacy intern
§16-95-86 Scope of practice of a pharmacy technician
§16-95-87 Return or exchange of drugs prohibited

Subchapter 11 Record Keeping Requirements

§16-95-93 Records of dispensing
§16-95-94 Automated data processing systems
§16-95-95 Security of records

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§16-95-96 Record keeping for wholesale prescription drug distributors

Subchapter 12 Advertising Practices

§16-95-101 Procedures to advertise prescription drugs
§16-95-102 Procedures to advertise related pharmacy services
§16-95-103 Advertising of controlled substances prohibited

Subchapter 13 Disciplinary Sanctions, Application Denial, Hearings, Administrative Practice and Procedure

§16-95-110 Grounds for revocation, suspension, refusal to renew or restore, denial, or conditioning of license or permit
§16-95-111 Denial
§16-95-112 Demand for hearing; proceedings upon demand for hearing
§16-95-113 Administrative practice and procedure

Subchapter 14 Oral Testimony

§16-95-118 Oral testimony

Subchapter 15 Fees

§16-95-123 Fees established
§16-95-124 Form of fee
§16-95-125 Dishonored checks considered failure to meet requirements

Subchapter 16 Emergency Contraception Collaborative Agreement

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§16-95-130 Emergency contraception written collaborative agreement

Subchapter 17 Dispensing of Refills During a State of Emergency without Practitioner's Authorization

§16-95-131 Procedure to dispense and refill without practitioner authorization

Subchapter 18 Prescription Drug Label Information Accessibility

§16-95-132 Drug label accessibility
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Subchapter 19 Remote Prescription Processing
§16-95-134 Remote Prescription Processing

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SUBCHAPTER 1

GENERAL PROVISIONS

§16-95-1 Objective; scope. This chapter is intended to clarify and implement chapter 461, Hawaii Revised Statutes, to the end that the provisions thereunder may be best effectuated and the public interest and welfare most effectively served and protected. Other requirements of state or federal law, including the laws enforced by the state department of health and department of public safety, which also may be applicable to the practice of pharmacy or to licensees, registrants, or permittees under chapter 461, HRS, are not encompassed within the scope of this chapter. [Eff 5/16/64; am and ren §16-95-1, 6/22/81; am and comp 12/24/92; comp 12/25/04; am

and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

§16-95-2 Definitions. As used in this chapter unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education, formerly known as the American Council on Pharmaceutical Education, which is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmacy education.

"Automated data processing system" or "ADP system" means a system utilizing computer software and hardware for the purpose of record keeping.

"Board" means the board of pharmacy.

"BREG" means the business registration division of the department.

"Department" means the department of commerce and consumer affairs.

"Director" means the director of commerce and consumer affairs.

"Dispense" or "dispensing" means the furnishing of drugs pursuant to a prescription in a suitable container, appropriately labeled for subsequent administration to, or use by, a patient or other individual entitled to receive the drug.

"HAR" means the Hawaii Administrative Rules.

"HRS" means the Hawaii Revised Statutes.

"Immediate supervision" means that a registered pharmacist is physically present in the area or location where a pharmacy intern or pharmacy technician is working and oversees the correctness and accuracy of the prescription's ingredients, quantity, and label.

"Institutional facility" includes a:

(1) Hospital;
(2) Convalescent home;
(3) Nursing home;
(4) Extended care facility;
(5) Mental institution;

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(6) Rehabilitation center;
(7) Health maintenance organization;
(8) Psychiatric center;
(9) Mental retardation center;
(10) Penal institution; or
(11) Any other organization whose primary purpose is to provide a physical environment for patients to obtain health care services or at-home care services, except those places where physicians, dentists, veterinarians, osteopaths, podiatrists, or other prescribers who are duly licensed, engage in private practice.

"Institutional pharmacy" means a pharmacy providing services to an institutional facility

[~~"NABPLEX" means the National Association of Boards of Pharmacy Licensure Examination, now known as the NAPLEX.~~]

"Nationally certified pharmacy technician" means an individual who has a Certified Pharmacy Technician certification from either the Pharmacy Technician Certification Board or National Healthcareer Association

"NAPLEX" means the North American Pharmacist Licensure Examination, previously known as the NABPLEX.

"Partnership" means a general partnership, a limited partnership, a limited liability partnership, or a limited liability limited partnership.

"Pharmacy intern" means a student or graduate of a school or college of pharmacy, that is accredited or is a candidate for accreditation by the ACPE, or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC®) Certificate, and who is issued a permit by the board to work under the immediate supervision of a registered pharmacist.

"**Registered** [~~P~~]pharmacy technician" means a [~~nonlicensed~~] registered individual, other than a pharmacy intern, who **is at least 16 years of age,** and assists the pharmacist in various activities under the immediate supervision of a registered pharmacist.

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"Remote processing" means the entering of an order or prescription into a computer from outside a pharmacy for a pharmacy licensed **in this State.**~~or permitted by the Board.~~

"Remote supervision" means supervision of a nationally certified pharmacy technician ~~and pharmacy interns~~ via technology that, at a minimum, ensures a pharmacist (1) is readily available to answer questions of the nationally certified pharmacy technician; and (2) verifies the work performed by the nationally certified pharmacy technician.

"Wholesale distribution" means the transfer of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales, defined as any transaction or transfer between an entity and any division, subsidiary, parent, or affiliated or related company under common ownership and control;

(2) The purchase or other acquisition, by an institutional facility that is a member of a group purchasing organization, of a drug for use by the entity's patient, from the group purchasing organization or from other institutional facilities that are members of the group purchasing organization;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986, as amended, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among institutional facilities that are under common control. For purposes of this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, working rights by contract, or otherwise;

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(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this paragraph, "emergency medical reasons" includes but is not limited to transfers of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary shortage, except that the gross dollar value of the transfers shall not exceed five per cent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any period of twelve consecutive months;

(6) The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives. For purposes of this paragraph, "drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug; or

(8) The sale, purchase, or trade of blood and blood components intended for transfusion. For purposes of this paragraph, "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing; and "blood component" means that part of blood separated by physical or mechanical means.

"Wholesale **prescription drug** distributor" means any person or entity in this State engaged in the transfer of prescription drugs to a person other than a consumer or patient, including but not limited to, manufacturers; repackers; own label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; practitioners; birth

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control and other clinics; individuals; hospitals; nursing homes and their providers; health maintenance organizations and other health care providers; and retail and hospital pharmacies that conduct wholesale distributions. The term "wholesale distributor" shall not include any carrier for hire or person or entity hired solely to transport prescription drugs. For purposes of this definition, "manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug; and "prescription drug" means any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act. [Eff 5/16/64; am 8/7/70; am and ren §16-95-2, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

§16-95-3 Repealed. [R 12/24/92]

§16-95-4 Repealed. [R 12/24/92]

§16-95-5 Repealed. [R 12/24/92]

§16-95-6 Repealed. [R 12/24/92]

§16-95-7 Repealed. [R 12/24/92]

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§16-95-8 Repealed. [R 12/24/92]

§16-95-9 Repealed. [R 12/24/92]

§16-95-10 Repealed. [R 12/24/92]

§16-95-11 Repealed. [R 12/24/92]

§16-95-12 Repealed. [R 12/24/92]

§16-95-13 Repealed. [R 12/24/92]

§16-95-14 Display of license or permit. The holder of a wholesale prescription drug distributor license, pharmacy technician registration, pharmacy permit, or miscellaneous permit shall conspicuously display, in the place of business, that license or permit and shall have the evidence of current validation in the holder's possession at all times. [Eff 5/16/64; am and ren §16-95-14, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §§[~~461-4~~], 461-9, 461-16) (Imp: HRS §§461-4, 461-9, 461-9.5, 461-16)

§16-95-15 Repealed. [R 12/24/92]

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§16-95-16 Repealed. [R 12/24/92]

§16-95-17 Repealed. [R 12/24/92]

§16-95-18 License or permit required. It shall be unlawful for a person who is not licensed or who has not been issued a permit under chapter 461, HRS, and this chapter to engage in the practice of a pharmacist, to perform the duties of a pharmacy intern, to operate a pharmacy, to engage in the wholesale distribution of drugs, or to engage in any activities requiring a miscellaneous permit. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-10)

§16-95-19 License or permit nontransferable. Any license or permit issued by the board shall be valid only for the person to which it is issued and shall not be transferable. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

SUBCHAPTER 2

APPLICATIONS

§16-95-21 Forms, documentation, and notification. (a) An application for license, [~~or~~] permit, or registration shall be made under oath on forms provided by the board and shall not be

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considered complete unless accompanied with the required documentation and fees. It shall be each applicant's responsibility to furnish all information and any documentation requested by the board.

(b) The application form may require the applicant and any personnel of the applicant to provide the following:

(1) The applicant's full name;

(2) A statement that the applicant has attained the age of majority~~.~~**, except that an applicant for a pharmacy technician registration shall be at least sixteen years of age**;

(3) The applicant's current business or mailing address for publication, and the applicant's current residence address;

(4) The applicant's social security number;

(5) The applicant's educational history and evidence of the education;

(6) The date and place of any conviction of a crime directly related to the practice of pharmacy, drugs, drug samples, wholesale or retail drug distribution, or distribution of controlled substances, unless the conviction has been expunged or annulled or is otherwise precluded from consideration by section 831-3.1, HRS;

(7) The state or states or United States territory in which the applicant is currently licensed, and any information regarding any disciplinary proceedings pending or disciplinary actions taken by any state or jurisdiction against the license;

(8) A statement that the applicant is a United States citizen or an alien authorized to work in the United States;

(9) The names, addresses, phone numbers, and social security numbers of corporate officers or partners or other personnel of the applicant;

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(10) Verification that the corporation, partnership, or entity is properly registered with BREG;

(11) Verification that the trade name, if any, is properly registered with BREG;

(12) The name and license number of the pharmacist in charge of the prescription area and the name or names and license number or numbers of any other pharmacists employed;

(13) The name, position, and title of any person responsible for the distribution of drugs; and

(14) Any other information the board may require to investigate the applicant's qualifications for license or permit.

(c) Any requirement that the board provide notice to licensees, registrants, or permittees shall be deemed met if notice is sent to the address on file with the board.

(d) Any change in the application or of any information filed with the board shall be reported to the board, in writing, within ten days of the change, including but not limited to address, name, officers, ownership, or pharmacist in charge.

(e) Upon closure of a pharmacy located in this State, the pharmacy shall:

(1) Provide written notice to the board within ten days; and

(2) Return all indicia of licensure. [Eff 5/16/64; am and ren §16-95-21, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5, 461-6, 461-7, 461-8.6, 461-14, 461-15)

Historical note: The substance of this section is based in part upon sections 16-95-13 and 16-95-35. [Eff 5/12/64; am and ren §§16-95-13, 16-95-35, 6/22/81; R 12/24/92]

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§16-95-22 Application and requirements for pharmacist license by examination. (a) An application for license by examination shall be accompanied by the required application fee, which shall not be refunded, and the examination fee. An examination fee may be refunded provided a written request for refund is made prior to the application deadline.

(b) An applicant shall:

~~(1)~~ Have attained the age of majority; and

~~(2)~~ Hold a degree from a school or college of pharmacy which has received candidate status with or has been accredited by the ACPE;

(c) For issuance of the license, the applicant shall provide evidence of:

~~(1)~~ At least fifteen hundred hours of practical experience; and

~~(2)~~ Passage of [~~either the NABPLEX or~~] the NAPLEX, and the Hawaii Multistate Pharmacy Jurisprudence Examination (MPJE) or either entity's successor recognized by the board. [~~The MPJE requires a passing score of at least seventy-five points.~~]

(d) An applicant who is a participant in the National Association of Boards of Pharmacy's (NABP) score transfer program shall be responsible for having the score report sent to the board.

(e) A foreign graduate, in addition to the requirements in subsections (a) to (d) and in lieu of the candidacy or accreditation requirements by the ACPE in subsection (b)(2), shall provide a Foreign Pharmacy Graduate Equivalency Committee™ (FPGEC®) Certificate. [~~verification of passing the following:~~

~~(1) The Foreign Pharmacy Graduate Equivalency Examination (FPGEE); and~~

~~(2) The Test of English as a Foreign Language (TOEFL)~~]; [Eff 5/16/64; am 3/16/80; am and ren §16-95-22, 6/22/81; am and comp 12/24/92; comp 12/25/04: am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-5, 461-6)

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§16-95-22.5 Application and requirements for pharmacist license by reciprocity. (a) An application for license by reciprocity shall be filed on forms provided by the board. The applicant shall submit:

(1) Evidence of current and valid licensure to practice pharmacy in another state or jurisdiction with qualifications which equal or exceed those of this State;

(2) Information regarding any disciplinary action taken or any complaints or investigations pending against the applicant;

(3) Evidence of having practiced for at least fifteen hundred hours as a licensed pharmacist within the five years preceding the date of application; and

(4) A completed official NABP licensure transfer application within ninety days from the date of issuance by the NABP, unless extended by the NABP.

(b) The board shall not issue a license by reciprocity unless the other state or jurisdiction grants reciprocal licensure to this state's licensees.

(c) The board may deny licensure by reciprocity if the applicant fails to fulfill the requirements herein or has had any disciplinary action taken or if any complaints are pending. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §461-8.5)

§16-95-23 Temporary license. (a) An application for temporary license may be filed at the same time as an application for examination and shall be accompanied by the non-refundable application fee. Following a determination by the board that the qualifications for admission to the examinations

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listed in section 461-6, HRS exist, a temporary license to practice pharmacy may be issued, provided the applicant:

(1) Passes the Hawaii MPJE [~~with a score of at least seventy-five points~~];

(2) Submits a verification, by an official of the licensing authority of that other state or territory of the United States, of a current and valid license to practice pharmacy in the other state or territory of the United States; and

(3) Submits evidence that the applicant has practiced for at least fifteen hundred hours as a licensed pharmacist within the five years preceding the date of application.

(b) The temporary license shall be valid only until the results of the next administration of [~~the NABPLEX or~~] the NAPLEX examinations are received by the board.

(c) The temporary license shall only remain in effect until the results of the next licensure examinations are announced; provided that the board may extend any temporary license, upon written request, and for good and just cause. Any applicant who fails to take or to pass the next licensure examination shall surrender the temporary license. The board shall receive a fee for the issuance of a temporary license. [~~In the event the pharmacist fails to take and pass [either] the [NABPLEX or] NAPLEX examination, the temporary license may be extended, for good and just cause, provided a request for extension is made in writing. In no case shall the temporary license be extended beyond three consecutive administrations of the examinations.~~] [Eff 5/16/64; am 3/16/80; am and ren §16-95-23, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §§461-4.5, 461-7) (Imp: HRS §§461-4.5, 461-7)

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§16-95-24 Pharmacy intern permit. (a) An application for a permit to work as a pharmacy intern may be filed at any time. The board may delegate to the board's executive officer the authority to issue a pharmacy intern permit to qualified applicants.

(b) An applicant shall provide verification that the applicant is currently enrolled in or is a graduate of a college of pharmacy which has received candidate status with or has been accredited by the ACPE[~~.~~], or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Equivalency Committee™ (FPGEC®) Certificate.

(c) An official transcript showing the date of graduation, or a letter from the dean or registrar that the applicant is currently enrolled at an ACPE accredited college of pharmacy shall be submitted with the application.

(d) The applicant shall provide the name and license number of the supervising pharmacist and the name and address of the pharmacy at which the applicant is employed or will be employed.

(e) The permit shall be valid for a maximum of six (6) years or two (2) years post-graduation, whichever comes first.

(f) [~~The Board shall maintain a list of active pharmacy intern permits on the board website.~~] The permit holder shall notify the Board and supervising pharmacist of withdraw or dismissal from the college of pharmacy within ten days. [Eff 5/16/64; am and ren §16-95-24, 6/22/81/; am and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5, 461-9)

Historical note: The substance of this section is based substantially upon sections 16-95-44 and 16-95-45. [Eff 5/16/64; am 8/7/70; am 6/11/77; am and ren §§16-95-44, 16-95-45, 6/22/81; R 12/24/92]

§16-95-25 Repealed. [R 12/24/92]

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§16-95-26 Pharmacy permit. (a) An application for a pharmacy permit shall be filed in duplicate at least fifteen days before a board meeting and must be accompanied by the application fee which shall not be refunded.

(b) In addition to providing information required by section 16-95-21(b), The application shall include:

[~~(1) A floor plan of the prescription area which shall diagram the space and location of fixtures such as counters, tables, drawers, shelves, storage cabinets including a locked cabinet, library, sink with hot and cold water, proper sewage outlet, and refrigeration storage equipment;~~]

(1) Type of business as differentiated on the board approved application including, but not limited to retail, inpatient hospital, compounding (sterile), compounding (non sterile), mail order, consulting, and specialty;

(2) The name and license number of the pharmacist in charge and any other pharmacists employed;

(3) A letter of verification or bill of sale that the pharmacy has been bought with the effective date of sale if the pharmacy was purchased;

(4) Evidence that the entity is currently registered with BREG. If a corporation, partnership, or limited liability company has been registered for more than one year, a "Certificate of Good Standing" from the department shall be attached. If a corporation, partnership, or limited liability company has been registered for less than one year, a "file-stamped" copy of the document filed with BREG shall be attached;

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(5) Evidence that the trade name, if any, is properly registered with BREG;

(6) An attestation that, at a minimum, the pharmacy possesses professional and technical equipment and supplies, sufficient space, references, and storage, to perform their line of business that meets the current industry standards. ~~The pharmacy shall have sufficient space, references, equipment and storage of prescription drugs and for the safe and proper compounding and/or preparing and dispensing of prescription drug orders.~~

(7) An attestation that, at a minimum, the pharmacy meets the following security requirements:

(A) Each pharmacist, while on duty, shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of drugs and/or devices.

(B) The pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at any time when the pharmacist is not present. In the event of separation of employment of an employee, suitable action shall be taken to ensure the safety of the pharmacy.

(C) Prescription and other patient health care information shall be maintained in a manner that protects the integrity and confidentiality of such information.

(D) The pharmacy shall implement and maintain processes and technologies that will aid in theft prevention, detection and investigation.

(8) Payment of non refundable fees specified by the board of pharmacy for the issuance of the license.

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[~~(6)An attestation that, at a minimum, the pharmacy possesses or has electronic access to the following reference materials:~~

~~(A) United States Pharmacopeia National Formulary, and all supplements;~~

~~(B) Federal Drug Enforcement Administration regulations;~~

~~(C) State uniform controlled substances laws, chapter 329, HRS.~~

~~(D) State food and drug laws, 328 HRS;~~

~~(E) State pharmacy law, chapter 461, HRS, and chapter 16-95 HAR;~~

~~(F) Prescription files and;~~

~~(G) Drug Facts and Comparison or other current drug information guide; and~~]

[~~(7) An attestation that, at a minimum, the pharmacy possesses the following technical equipment and supplies:~~

~~(A) Class A prescription balance or a balance of greater sensitivity and appropriate weights;~~

~~(B) Mortar and pestle (glass or porcelain);~~

~~(C) Refrigerator;~~

~~(D) Bottles and vials of assorted sizes;~~

~~(E) Graduates or other similar measuring device; and~~

~~(F) Prescription labels.~~]

(c) No permit shall be issued unless all deficiencies have been corrected and approved by the board.

(d) The board may delegate to its executive officer the authority to issue a permit upon receipt of a completed application and documentation evidencing clear compliance with this section. [Eff 5/16/64; am and ren §16-95-26, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-12, 461-14)

Historical note: The substance of this section is substantially based upon section 16-95-51. [Eff

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5/16/64; am 6/11/77; am and ren §16-95-51, 6/22/81; R 12/24/92]

§16-95-27 Repealed. [R 12/24/92]

§16-95-28 Repealed. [R 12/24/92]

§16-95-29 Repealed. [R 12/24/92]

§16-95-30 Wholesale prescription drug distributor license requirements. (a) Application for a wholesale prescription drug distributor license shall be made under oath on a form to be provided by the board. In addition to providing information required by section 16-95-21(b), the applicant shall provide the following information as it pertains to the applicant including any officer, director, manager, or other persons in charge of wholesale drug distribution, storage, or handling:

(1) Any convictions under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony conviction under federal, state, or local laws;

[~~(3) Each person's past experience in the manufacture or distribution of prescription and controlled drugs;~~]

(3)[~~(4)~~] Any suspension, revocation, disciplinary action, or pending investigation by any federal, state, or local government of any license currently or previously held for the manufacture or

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distribution of any drugs, including controlled substances;

(4)[~~(5)~~] Verification of at least one year of experience in the distribution or handling of prescription drugs for any person responsible for the distribution of drugs; and

(5)[~~(6)~~] A current list of officers, directors, managers, and other persons in charge of the wholesale distribution, storage, and handling of prescription drugs, including a description of each person's duties and a summary of each person's qualifications.

(b) A map of the facilities shall also be submitted. The map shall identify:

(1) The storage area for drugs;

(2) The storage area for quarantined drugs; and

(3) The placement of the lighting, ventilation, and temperature control equipment.

(c) No license shall be issued prior to receipt of a satisfactory inspection report from the state department of health. At a minimum, the board requests that the department of health shall ensure that:

(1) The facilities are of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) The storage areas are designed to provide adequate ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) A quarantine area is available for prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or whose immediate or sealed outer or sealed secondary containers have been opened;

(4) The facility is maintained in a clean and orderly fashion;

(5) The facility is free from infestation by insects, rodents, birds, or vermin of any kind;

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(6) The facility is secure from unauthorized entry;
(7) Access from outside the premises is kept to a minimum and well controlled;
(8) The outside perimeter of the premises is well-lighted;
(9) Entry into areas where prescription drugs are held is limited to authorized personnel;
(10) The facilities are equipped with an alarm system to detect entry after hours;
(11) The facilities are equipped with a security system that will provide suitable protection against theft and diversion;
(12) All prescription drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of the drugs, or in accordance with the standards regarding conditions and temperatures for the storage of prescription drugs adopted by the state department of health.
    (A) If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature, as defined in the current United States Pharmacopeia National Formulary and all supplements, to help ensure that its identity, strength, quality, and purity are not adversely affected;
    (B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document the proper storage of prescription drugs;
(13) Upon receipt, each outside shipping container of prescription drugs is examined visually to confirm the identity of the drugs and to prevent the acceptance of contaminated prescription drugs that are unfit for distribution. This examination shall be adequate to reveal container damage

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that would suggest possible contamination or other damage to the contents;

(14) Each outgoing shipment of prescription drugs is inspected carefully to confirm the identity of the drugs and to ensure that no prescription drugs are delivered that have been damaged in storage or held under improper conditions;

(15) Returned, damaged, outdated, deteriorated, mishandled, or adulterated prescription drugs are physically separated from other prescription drugs and stored, in such a way that no cross contamination or confusion is possible, until they are destroyed or returned to the supplier;

(16) Any prescription drugs whose immediate or sealed outer or sealed secondary containers are found upon arrival to have been opened or used are identified as such, and are physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion is possible, until they are destroyed or returned to the supplier; and

(17) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug is either destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container,

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carton, or labeling as a result of storage or shipping.

(d) Written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories shall be submitted. Written policies and procedures shall include:

(1) A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;

(2) A procedure for handling recalls and withdrawals of prescription drugs. The procedures shall be adequate to deal with recalls and withdrawals caused by:

(A) Any action initiated at the request of the department of health, the Food and Drug Administration, or any other federal, state, or local law enforcement or other government agency;

(B) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(C) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) A procedure to ensure that the distributor prepares for, protects against, and handles properly any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or in other emergencies; and

(4) A procedure to ensure that all outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or destroyed. This procedure

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shall require written documentation of the disposition of outdated prescription drugs. The documentation shall be maintained for five years after disposition of the outdated drugs. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: §461-4.5)

§16-95-31 Miscellaneous permit. (a) An application for a miscellaneous permit shall be filed at least fifteen days before a board meeting and shall be accompanied by the application fee, which shall not be refunded, and required fees.

(b) In addition to providing information required by section 16-95-21(b), the application shall include:

(1) Type of business as differentiated on the board approved application including, but not limited to mail order, sterile compounding, non-sterile compounding, consulting, specialty, outsourcing facility registered under the Section 503B of the Federal Food, Drug, and Cosmetic Act, Section, or wholesale prescription drug distributor.

(2) Based on the type of business, provide the two most recent certifications and documentation required by the respective agency with which the applicant is licensed, registered, or otherwise subject to compliance with applicable federal or state laws, including but not limited to, Boards of Pharmacy, the United States Food and Drug Administration, or the United States Pharmacopeia chapters.

(3) Verification of a valid, unexpired license, permit or registration in good standing to operate the pharmacy or entity, including but not limited to wholesale prescription

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drug distributors, in compliance with all federal and state laws of the home state.

(4) The name of the pharmacist in charge and the names of any other employed pharmacists, along with verification of each pharmacist's valid, current license in good standing from the applicant's domicile Board of Pharmacy;

(5) Provide the location, names and titles of all principal corporate officers; and

(6) Attestation that the applicant and any personnel of the applicant has not been found in violation of any state or federal drug laws, including the illegal use of drugs or improper distribution of drugs.

(c) A change in the type of business shall require the filing of a new application with the Board.

[Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-15, 461-16)

§16-95-32 Criminal conviction. When an applicant or the applicant's personnel has been convicted of a crime related to the pharmacy profession and it is determined that the conviction may be considered under section 831-3.1, HRS, the board may request the following documents from the applicant:

(1) Copies of any court records, judgments, orders, or other documents that state the facts and statutes upon which the applicant was convicted, the judgment of the court with regard to that conviction, the sentence imposed, and the record of compliance with the sentence imposed; and

(2) Affidavits from any parole officer, employer, or other persons who can attest to a firm belief that the applicant has been sufficiently rehabilitated to warrant the

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public trust. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-21)

§16-95-32.2 Denial or rejection of application. (a) An application for issuance of a license, registration, or permit shall be denied when an application is insufficient or incomplete; is not accompanied with the required fees; or when an applicant has failed to provide satisfactory proof that the applicant meets the requirements for the license, registration, or permit. In addition, the board may deny issuance of a license, registration, or permit in accordance with sections 436B-19 and 461-21, HRS, and section 16-95-110.

(b) An application shall be automatically rejected and the applicant shall be denied a license, registration, or permit when the applicant, after having been notified to do so:

(1) Fails to pay the appropriate fees within sixty days from notification; or

(2) After being requested by the board, fails to provide any information or documentation concerning the requirements for licensure, registration, or permit within sixty days of the request.

(c) Any application which has been denied or rejected shall remain in the possession of the board and shall not be returned.

(d) An applicant, whose application has been denied or rejected, may file for an administrative hearing pursuant to chapter 91, HRS. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5, 461-14, 461-15, 461-21)

SUBCHAPTER 3

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EDUCATION AND EXPERIENCE DOCUMENTATION

§16-95-33 Education documentation for a pharmacist license. (a) The board will accept the following as verification of education requirements for a pharmacist:

(1) A certified copy of an official transcript showing the date of graduation from a college of pharmacy which has received candidate status with or has been accredited by the ACPE;

(2) In lieu of the requirements of paragraph (1), at the time of application, the board will accept a certified letter from the college registrar or dean verifying that the applicant is on track to graduate. However, prior to the issuance of the license, the applicant shall have complied with chapter 461, HRS, and shall have provided a certified copy of an official transcript from a college of pharmacy, which has received candidate status with or has been accredited by the ACPE and has been conferred a degree.

~~(b)~~ The board will accept online verification of the Foreign Pharmacy Graduate Equivalency Committee™ (FPGEC®) Certification ~~the following~~ as verification of education requirements from a foreign graduate: [

~~(1) A certified copy of the foreign diploma or a certified copy or official transcript showing the date of graduation from the foreign college of pharmacy; and~~

~~(2) An original or certified copy of the certificates evidencing the passage of the FPGEE examination.~~]

[Eff 5/16/64; am 6/11/77; am and ren §16-95-33, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §461-5)

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§16-95-33.2 Education documentation for a pharmacy intern permit. The board will accept the following as verification of education requirements for a pharmacy intern permit:

(1) A certified copy of an official transcript showing the date of graduation from a college of pharmacy which has received candidate status with or has been accredited by the ACPE; or

(2) A verification letter from the college dean or registrar that the applicant is currently enrolled at a school or college of pharmacy which has received candidate status with or has been accredited by the ACPE. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5, 461-9)

Historical note: The substance of this section is based substantially upon sections 16-95-44 and 16-95-45. [Eff 5/16/64; am 8/7/70; am 6/11/77; am and ren §§16-95-44, 16-95-45, 6/22/81; R 12/24/92]

§16-95-34 Experience verification for a pharmacist by examination. (a) An applicant shall have at least fifteen hundred hours of practical experience under the supervision of a registered pharmacist. Practical experience shall have been acquired subsequent to graduation or completion of the first year's attendance at a school or college of pharmacy which has received candidate status with or has been accredited by the ACPE and may include:

(1) Post graduate experience;

(2) Supervised practice during vacations;

(3) Experience gained concurrent with attendance at a pharmacy school; and

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(4) Experience gained during pharmacy school coordinated externships and clinical clerkship programs.

(A) For purposes of this section, externship means a pharmacy school coordinated practical experience program which was:

(i) Conducted outside the classroom in licensed pharmacies;

(ii) Developed to provide a broad experience in all distributive and patient oriented practice tasks;

(iii) Supervised by a licensed preceptor or licensed pharmacist with a one to one teaching and supervisory relationship between the preceptor or pharmacist and the extern; and

(iv) A component of the pharmacy school's curriculum for which academic credit is given.

(B) For purposes of this section, clinical clerkship means a pharmacy school coordinated practical experience program which:

(i) Was conducted in patient care settings where the student is provided with actual experience in patient care;

(ii) Placed emphasis on all phases of drug therapy relative to the disease states of individual patients;

(iii) Provided clinical service on either an outpatient or an inpatient basis as a primary student activity;

(iv) May minimize general drug distributive functions; and

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(v) Is a component of the pharmacy school's curriculum for which academic credit is given.

(b) The board will accept a written statement of practical experience, signed by an official of the licensing authority of another state, the pharmacy school, the employing pharmacy, or the supervising pharmacist who is licensed in any state or territory of the United States, attesting that the applicant worked under the immediate supervision of the pharmacist in a pharmacy in the United States or territory of the United States, selling drugs, billing prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under state and federal statutes. The statement shall also show the beginning and ending dates of the applicant's practical experience and the total number of hours worked.

(c) The board will not accept any pro gratis practical experience hours granted upon graduation for which an applicant has not actually worked. [Eff 5/16/64; am 6/11/77; am and ren §16-95-34, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5)

Historical note: The substance of this section is based substantially upon sections 16-95-44, 16-95-45 and 16-95-47. [Eff 5/16/64; am 8/7/70; am 6/11/77; am and ren §§16-95-44, 16-95-45, 16-95-47, 6/22/81; R 12/24/92]

§16-95-35 Repealed. [R 12/24/92]

§16-95-36 Experience verification for a pharmacist license by reciprocity or temporary pharmacist license. The applicant for a pharmacist license by reciprocity shall provide proof of current

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licensure and at least fifteen hundred hours of practical experience as a registered pharmacist within five years preceding the date of application in the form of:

(1) A statement signed by an official of the licensing authority from another state or territory of the United States, attesting that the license is current, is valid, unencumbered, and in good standing and a statement signed by the applicant's employer or employers attesting that the applicant has practiced pharmacy as a licensed pharmacist for fifteen hundred hours or more within the five years preceding the date of application; or

(2) If the applicant is self-employed, a statement by the applicant attesting that the applicant owned and operated an independent pharmacy and that the applicant has practiced pharmacy as a licensed pharmacist for fifteen hundred hours or more within the five years preceding the date of application. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-5, 461-8.5)

[REINSTATE (1) and (2) PREVIOUSLY REMOVED AND REVERT TO ORIGINAL]

SUBCHAPTER 4 - REPEALED

§16-95-39 Repealed. [R 12/24/92]

§16-95-40 Repealed. [R 12/24/92]

§16-95-41 Repealed. [R 9/28/04]

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§16-95-42 Repealed. [R 9/28/04]

§16-95-43 Repealed. [R 9/28/04]

SUBCHAPTER 5 – REPEALED

§16-95-44 Repealed. [R 12/24/92]

§16-95-45 Repealed. [R 12/24/92]

§16-95-46 Repealed. [R 12/24/92]

§16-95-47 Repealed. [R 12/24/92]

§16-95-48 Repealed. [R 12/24/92]

§16-95-49 Repealed. [R 12/24/92]

§16-95-50 Repealed. [R 12/24/92]

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SUBCHAPTER 6 – REPEALED

§16-95-51 Repealed. [R 12/24/92]

§16-95-52 Repealed. [R 12/24/92]

§16-95-53 Repealed. [R 12/24/92]

§16-95-54. Repealed. [R 12/24/92]

SUBCHAPTER 7 – REPEALED

§16-95-55 Repealed. [R 12/24/92]

§16-95-56 Repealed. [R 12/24/92]

§16-96-57 Repealed. [R 12/24/92]

§16-95-58 Repealed. [R 12/24/92]

§16-95-59 Repealed. [R 12/24/92]

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§16-95-60 Repealed. [R 12/24/92]

§16-95-61 Repealed. [R 12/24/92]

§16-95-62 Repealed. [R 12/24/92]

§16-95-63 Repealed. [R 12/24/92]

§16-95-64 Repealed. [R12/24/92]

SUBCHAPTER 8 - REPEALED

§16-95-65 Repealed. [R 12/24/92]

SUBCHAPTER 9

RENEWAL

§16-95-70 Repealed [R 03/12/15]

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§16-95-71 Date for filing. All licensees, registrants, and permit holders shall complete and submit a renewal application together with the required fees on or before December 31 of the odd-numbered year. A completed renewal application with the required fees sent by the United States mail shall be considered timely filed if the envelope bears a postmark no later than December 31 of the -odd numbered year or if filed on-line with the department by that date. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-8, 461-16)

Historical note: The substance of this section is based in part upon section 16-95-15. [Eff 5/16/64; am and ren §16-95-15, 6/22/81; R 12/24/92]

§16-95-72 Automatic forfeiture for failing to renew. The failure to timely renew the license, registration, or permit or to pay the applicable fees or paying fees with a check which is dishonored upon first deposit shall cause the license, registration, or permit to be automatically forfeited. [Eff and comp 12/24/92; comp 12/25/04; comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-8, 461-16, Act 196, SLH 1992)

§16-95-73 Restoration of forfeited license or permit. (a) A forfeited pharmacist license may be restored within three years of the forfeiture provided the applicant:

(1) Within the first year of the forfeiture:

(A) Applies for restoration on a ~~from~~ form provided by the board;

(B) Pays the penalty, current biennial and renewal fees; and

(C) Complies with the continuing education requirements under section 461-8, HRS;

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(2) Within the second and third year of the forfeiture:

(A) Applies for restoration on a form provided by the board;

(B) Pays the penalty, current biennial and renewal fees;

(C) Complies with the continuing education requirements under section 461-8, HRS; and

(D) If the applicant has been actively engaged in the practice of pharmacy in this state or another state within the five years preceding the restoration application, the applicant:

(i) Provides evidence of good standing in all states in which the applicant is or has been licensed; and

(ii) Provides evidence of having practiced for at least fifteen hundred hours as a licensed pharmacist;

(E) If the applicant has not been actively engaged in the practice of pharmacy in this state or another state within the five years preceding the restoration application, the applicant:

(i) Provides evidence of having practiced for at least fifteen hundred hours as a licensed pharmacist; and,

(ii) Takes and passes the Hawaii MPJE.

~~[(2) Within the second and third year of the forfeiture:~~

~~(A) Applies for restoration on a form provided by the board;~~

~~(B) Submits an official statement signed by the applicant's employer or employers or if the applicant was self-employed, a statement signed by the applicant attesting that the applicant has been employed for a minimum of fifteen hundred hours as a licensed pharmacist within the five years preceding the date of application;~~

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~~(C) If applicable, provides a statement signed by a licensing official of each other state or territory of the United States in which a license is held or once held, indicating that the license is current, valid, unencumbered, and in good standing or, if the license is not current, valid, and unencumbered, whether any disciplinary action had been taken against the licensee. The applicant shall be responsible for obtaining any additional information required by the board to review the reasons the license is not current, valid, unencumbered, or in good standing;~~

~~(D) Takes and passes the Hawaii MPJE;~~

~~(E) Pays the penalty, current biennial, and renewal fees; and~~

~~(F) Complies with the continuing education requirements under section 461-8, HRS.~~]

(b) A forfeited pharmacy or miscellaneous permit, or a wholesale distributor license may be restored within three years of the forfeiture, provided the applicant:

(1) Applies for restoration on a form provided by the board;

(2) Pays all penalty fees, current biennial, and renewal fees;

(3) Submits a signed statement to report changes, if any, to the information on file with the board; and

(4) In the case of a wholesale distributor, passes a facility inspection conducted by the department of health.

(c) The board may deny restoration of a forfeited license or permit if during the time the license or permit was forfeited, the license or permit holder engaged in any activities identified in section 436B-19 or 461-21, HRS, or both.

(d) A person whose license, registration, or permit has been forfeited and who fails to restore the

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license or permit as provided in this section, shall apply as a new applicant. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-8, 461-16)

Historical note: The substance of this section is based substantially upon sections 16-95-16 and 16-95-17. [Eff 5/16/64; am 3/16/80; am and ren §§16-95-16, 16-95-17, 6/22/81; R 12/24/92]

§16-95-74 Board may refuse to renew or restore a license or permit. (a) The board may refuse to renew or restore a license or permit for failure or refusal of the licensee or permit holder to:

(1) Properly complete or timely submit the renewal application form and submit all fees and required documentation;

(2) Meet and maintain the conditions and requirements necessary to qualify for the issuance of the license or permit; and

(3) Comply with chapter 461, HRS, and this chapter.

(b) An applicant, whose application has not been renewed or restored for the reasons stated in subsection (a), may file for an administrative hearing pursuant to chapter 91, HRS. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

SUBCHAPTER 10

SCOPE OF PRACTICE

§16-95-79 Supervision by a registered pharmacist. (a) A registered pharmacist shall [~~immediately~~]supervise all activities and operations of

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a pharmacy, and [~~immediately~~] supervise the functions and activities of pharmacy interns and pharmacy technicians in accordance with this chapter, to ensure that all functions and activities are performed in accordance with laws and rules governing the practice of pharmacy.

(b) A pharmacist either employed within an institutional facility or providing services to an institutional facility shall be responsible for ensuring that the institutional facility establishes, maintains, and operates in accordance with written policies and procedures as outlined in section 16-95-80. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-9, 461-10, 461-11, 461-12, 461-13)

Historical note: The substance of this section is based in part on section 16-95-46. [Eff 5/16/64; am and ren §16-95-46, 6/22/81; R 12/24/92]

§16-95-80 Physical presence of a registered pharmacist. (a) A registered pharmacist shall be physically present during the hours of operation of a prescription area.

(b) At any time a registered pharmacist is not in the prescription area, (except in cases of emergencies), the entire stock of prescription drugs shall be secured from access to unauthorized persons and the means of access shall only be in the control of the pharmacist.

(c) A pharmacist in an institutional pharmacy shall ensure that written policies and procedures have been established by the institutional facility for providing drugs to the medical staff and other authorized personnel of the institutional facility by use of night cabinets, and access to the institutional pharmacy and emergency kits when the pharmacist is not in the area. A "night cabinet" is a cabinet, room, or any other enclosure not located within the

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prescription area. The written policies and procedures shall provide that a pharmacist shall be "on call" during those periods when night cabinets are utilized and shall provide policies and procedures regarding the following:

(1) Security of the night cabinet to ensure that the night cabinet is sufficiently secured to deny access to unauthorized persons by force or otherwise;

(2) The development and maintenance of an inventory listing of all drugs included in the cabinet and the requirement that the pharmacist ensures, at a minimum, that:

(A) Drugs available therein are properly labeled;

(B) Only prepackaged drugs are available therein in amounts sufficient for immediate therapeutic requirements; and

(C) An appropriate practitioner's prescription regarding the dispensing of drugs exists;

(3) Access to the pharmacy. In the event a drug is not available from floor supplies or night cabinets and the drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the institutional pharmacy in accordance with this subsection. Authorized personnel may remove drugs therefrom provided:

(A) The authorized personnel are designated, in writing, by the institutional facility;

(B) The authorized personnel have been instructed by the pharmacist of the proper methods of access, and the records and procedures regarding removal of the drugs; and

(C) The authorized personnel are required to complete a form which shall include the patient's name and room number, the name of drug, drug strength, dosage,

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quantity of drug removed, date, time, and the signature of the authorized personnel; and

(4) The prompt detection, removal, disposal, handling, and replacement, if possible, of a drug that has been recalled by the U.S. Food and Drug Administration or the manufacturer to ensure that recalled drugs are removed from the pharmacy's inventory, emergency kit, night cabinet, remote dispensing machine, or from the patient if deemed necessary according to the federal and manufacturer's guidelines. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-1, 461-4.5, 461-9, 461-10, 461-11, 461-12)

Historical note: The substance of this section is based in part on section 16-95-4. [Eff 5/16/64; am and ren §16-95-4, 6/22/81; R 12/24/92]

§16-95-81 Emergency kits. (a) A pharmacist may provide emergency kits to an institutional facility which does not have an institutional pharmacy to meet the immediate therapeutic needs of patients.

(b) The pharmacist and the medical staff of the institutional facility shall jointly determine the drugs, and quantity, to be included in the emergency kit.

(c) The exterior of emergency kits shall be labeled by the pharmacist to clearly indicate that the kit is an emergency drug kit. There shall be a listing of the drugs contained in the emergency kit, including name, strength, quantity, and expiration date of the drugs, which shall be maintained and kept in an accessible location near to the emergency kit, along with the name, address, and telephone number of the supplying pharmacy.

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(d) All drugs contained within the emergency kit shall be labeled to identify, at a minimum, the brand or generic name, strength, route of administration, if other than oral, quantity, source, manufacturer, if generic, lot number, expiration date, and other information as may be required by the medical staff of the institutional facility to prevent any misunderstanding or risk of harm to the patients of the facility.

(e) On or before the earliest expiration date of any drug contained in the emergency kit, the pharmacist shall replace any expired drugs, relabel, and reseal the kit.

(f) The pharmacist shall ensure that the institutional facility has established written policies and procedures which shall provide, but not be limited to, policies and procedures covering:

(1) Storage of emergency kits in secured areas which shall be in an environment for preservation of the drugs;

(2) Procedures to ensure that drugs are removed only pursuant to a valid prescription or practitioner's order and recordation of any removal; and

(3) Procedures to notify the pharmacist within twenty-four hours of any removal of any drug from the emergency kit. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-1, 461-9, 461-10, 461-11, 461-12)

§16-95-82 Valid prescriptions. (a) A pharmacist may fill and dispense prescriptions provided the prescription is valid. A valid prescription shall [~~be legibly written and~~] contain, at a minimum, the following information:

(1) The date of issuance;

(2) The original <u>or electronic</u> signature of the practitioner;

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(3) The practitioner's name and business address;
(4) The name, strength, quantity, and specific instructions for the drug to be dispensed;
(5) The name and address of the person for whom the prescription was written or the name of the animal and address of the owner of the animal for which the drug is prescribed, unless the pharmacy filling the prescription has such address on file;
(6) The room number and route of administration if the patient is in an institutional facility; and
(7) If refillable, the number of allowable refills.

(b) Except where a written prescription is required by law, a practitioner or the practitioner's agent may use a phone order, provided:
(1) Only a pharmacist or a pharmacy intern shall receive the oral prescription;
(2) The oral prescription shall be immediately reduced to writing, including the practitioner's oral code designation, by the pharmacist or pharmacy intern and shall be kept on file for five years; and
(3) The oral prescription contains all of the information required under subsection (a).

(c) A faxed prescription for a noncontrolled substance sent by a practitioner or the practitioner's agent is acceptable provided it contains all of the information required under subsection (a) and is kept on file for five years.

(d) Any pharmacist shall comply with any applicable state or federal laws or rules governing the validity of prescriptions. [Eff and comp 12/24/92; comp 12/25/04 ; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-11, 461-13)

Historical note: The substance of this section is based in part upon sections 16-95-9 and 16-95-10.

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[Eff 5/16/64; am and ren §§16-95-9, 16-95-10, 6/22/81; R 12/24/92]

§16-95-83 Substitution; drug product selection. (a) It shall be unlawful to dispense a different drug in place of the drug prescribed without the express consent of the person prescribing.

(b) Drug product selection shall comply with part VI of chapter 328, HRS. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§328-92, 328-94, 328-97, 328-98, 461-11, 461-13, 328)

Historical note: The substance of this section is based in part upon section 16-95-83 is based substantially upon §16-95-11. [Eff 5/16/64; am and ren §16-95-11, 6/22/81; R 12/24/92]

§16-95-84 Transfer of prescriptions. (a) Transfers of prescription information for the purpose of initial fill or refill dispensing is permissible between pharmacies provided the pharmacist transferring the prescription provides all information necessary for a valid prescription, and records on the prescription, the name and location of the pharmacy receiving the prescription, the name of the pharmacist receiving the prescription information, the date of transfer, and the name of the pharmacist transferring the prescription, or notes the pharmacist's name on the electronic files, and records that the prescription is inactivated or made void for future refills at the location from which it is being transferred.

(b) The pharmacist receiving the transferred prescription information shall indicate the name of the pharmacist transferring the prescription as well as the transferring pharmacist's or pharmacy name, the transferring pharmacy's name, location, and original

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prescription number, the original date the prescription was written, the number of refills or quantity remaining on the prescription, and the last date the prescription was filled.

(c) All records of transferred prescriptions shall be maintained for a period of five years from the date of filling or refilling.

(d) Electronic and transfers by facsimile are also permitted. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-10, 461-11, 461-13)

§16-95-85 Scope of practice of a pharmacy intern. A pharmacy intern may perform all functions under the definition of "practice of pharmacy" as stated in section 461-1, HRS, except where prohibited by any state or federal law or rule and excluding the final drug verification before it is dispensed. The pharmacy intern shall at all times be under the immediate supervision of a licensed or registered pharmacist. [Eff and comp 06/22/15; comp 8/15/16] (Auth: HRS §461.9) (Imp: HRS §§461-4.5, 461-9)

§16-95-86 Scope of practice of a pharmacy technician. (a) A registered pharmacy technician and a nationally certified pharmacy technician may perform the following tasks, not requiring professional judgment, under the immediate supervision of a pharmacist:

(1) Process prescription labels, drug packaging, stocking, delivery, record keeping, pricing, documentation of third party reimbursements, and preparing, labeling, compounding, storing, and providing medication; and

(2) Medication preparation is permissible provided that the pharmacy technician:

(A) Has a working knowledge of the pharmaceutical medical terms,

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abbreviations, and symbols commonly used in the prescribing, dispensing, and charting of medications;

(B) Is able to perform the arithmetic calculations required for the usual dosage determination and solution preparation;

(C) Has a thorough knowledge and understanding of the pharmacy technician's duties and responsibilities, including standards of ethics and applicable laws and regulations governing the practice of pharmacy;

(D) Has a working knowledge of drug dosages, route of administration, and dosage forms and therapeutics;

(E) Has a working knowledge of the procedures and operations relating to the manufacturing, packaging, and labeling of drug products; and

(F) Has an appropriate working knowledge of the procedures and operations relating to aseptic compounding and parenteral admixture operations.

(3) Administer vaccines for persons three years of age or older provided that: ~~requirements stated in 461-11.4, HRS, are met.~~

(A) the registered technician is at least 18 years of age; and

(B) requirements stated in 461-11.4, HRS, are met.

(b) A nationally certified registered pharmacy technician may also perform the following tasks, not requiring professional judgment, under the remote supervision of a pharmacist:

(1) Prescription or order entry, other data entry, insurance processing of prescriptions and medication orders, and record keeping as authorized for Remote Prescription Processing in §16-95-134;

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(2) Transmitting orders on behalf of the pharmacist;

(3) Communicating with patients and providers regarding information including but not limited to, verifying patient and provider information, collecting patient-reported information (e.g., medications, self-monitored test results such as vitals and blood sugar readings, patient questionnaires, etc.), relaying information from the pharmacist to the patient, follow-up scheduling or reminders (e.g., refills, lab tests, appointments, etc.), billing, pricing, initial and refill requests, prior authorizations, rejections, and order status; and

(4) Inventory management of clinic administered medication in areas that provide direct patient care.

[Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-9, 461-10, 461-11)

§16-95-87 Return or exchange of drugs prohibited. No prescription drug shall be accepted for return or exchange after the drug has been taken from the premises where dispensed or sold by prescription. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §461-11)

Historical note: Section 16-95-87 is substantially identical to section 16-95-12. [Eff 5/15/64; am and ren §16-95-12, 6/22/81; R 12/24/92]

SUBCHAPTER 11

RECORD KEEPING REQUIREMENTS

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§16-95-93 Records of dispensing. (a) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for five years and, in addition to the requirements of section 16-95-82, shall include but not be limited to the following:

(1) Quantity prescribed and quantity dispensed;
(2) Date of dispensing;
(3) Serial number or, if an institution, equivalent control system;
(4) Identification of the pharmacist responsible for dispensing; and
(5) Record of refills to date.

(b) An institutional pharmacy will have fulfilled the requirements of this section if the information required by subsection (a)(1) to (4) is kept on accurate patient profiles or medication administration records showing all drugs administered to the patient for five years; and the institutional facility keeps the original patient charts evidencing the prescription orders and medication administration records in the institutional facility's files for at least five years. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-10, 461-11, 461-13)

§16-95-94 Automated data processing systems. As an alternative to procedures set forth in section16-95-93, an ADP system may be employed for the record keeping system provided the following conditions have been met:

(1) The ADP system shall have the capability of producing hard copy documents of all drug orders of original and refilled prescription information. The hard copy produced must be of a print size that is readable without the aid of any special device;

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(2) Information to be kept on the ADP system shall include, but not be limited to the information required in section 16-95-82, valid prescriptions, and section 16-95-93, records of dispensing;

(3) The pharmacist responsible for entries into the ADP system shall ensure that the information entered into the computer is accurate and complete;

(4) The documentation used to satisfy the above requirements shall be provided to the pharmacy within seventy-two hours of the date of dispensing;

(5) An auxiliary record keeping system shall be established for the documentation of refills in the event the ADP system is inoperative for any reason. The auxiliary system shall ensure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When the ADP system is restored to operation, the information regarding drug orders and prescriptions filled and refilled during the inoperative period shall be entered in the ADP system within ninety-six hours;

(6) Any pharmacy using an ADP system shall comply with all applicable state and federal laws, rules, and regulations; and

(7) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete records for any drug order, prescription, and dispensing if the relationship with such supplier terminates for any reason. The pharmacy shall assure continuity in the maintenance of records. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-9, 461-10, 461-11, 461-12, 461-13)

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§16-95-95 Security of records. To maintain the confidentiality of patient's prescriptions or drug orders, there shall exist adequate safeguards for security of the records whether kept manually or in an ADP system. [Eff and comp 12/24/92; comp 12/25/04; comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-9, 461-10, 461-11, 461-12, 461-13)

§16-95-96 Record keeping for wholesale prescription drug distributors. (a) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These inventories and records shall include the following information:

(1) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(2) The identity and quantity of the drugs received and distributed or disposed of; and

(3) The dates of receipt and distribution or other disposition of the drugs.

(b) The wholesale distributor shall also maintain records to reflect:

(1) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with the requirements, if any, in the labeling of the drugs, or in accordance with the standards regarding conditions and temperatures for the storage of prescription drugs.

(A) If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature, as defined in an official

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compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document the proper storage of prescription drugs.

(2) Examination of materials.

(A) Documentation shall be maintained for at least five years demonstrating that each outside shipping container of prescription drugs was examined visually to confirm the identity of the drugs and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution shall be maintained. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(B) Documentation shall be maintained for at least five years demonstrating that each outgoing shipment of prescription drugs was inspected carefully to confirm the identity of the drugs and to ensure that no prescription drugs were delivered that have been damaged in storage or held under improper conditions.

(3) Returned, damaged, outdated, deteriorated, misbranded, and adulterated prescription drugs.

(A) Prescription drugs that are damaged, outdated, deteriorated, misbranded, or adulterated shall be physically separate from other prescription drugs and stored, in such a way that no cross-contamination or confusion are

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possible, until they are destroyed or returned to the supplier.

(B) Any prescription drugs whose immediate or sealed outer or sealed secondary containers are found upon arrival to have been opened or used shall be identified as such, and shall be physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion are possible, until they are destroyed or returned to the supplier.

(C) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be either destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

(c) Inventories and records shall be made available for inspection and photocopying by the department or any authorized federal, state, or local law enforcement officials for a period of five years following disposition of the drugs.

(d) Records described in this section that are kept at the inspection site or that can be retrieved immediately by computer or other electronic means

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shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by the department or any authorized official of a federal, state, or local law enforcement agency. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5)

SUBCHAPTER 12

ADVERTISING PRACTICES

§16-95-101 Procedures to advertise prescription drugs. (a) Advertising of prescription drugs is to provide the public with information in a manner consistent with public health and safety. Prescription drug advertising is for the purpose of providing information and not to create a demand for drugs. A pharmacy, if it chooses to advertise, will advertise prescription prices, drugs, and reference to prescription prices and drugs in accordance with this section:

(1) A pharmacy may post its prices for prescription drugs on a prescription price poster. The form of the posting shall be legible;

(2) A pharmacy may advertise prescription prices by publication or display in any media. For purposes of this section, "media" includes but is not limited to newspapers, magazines, calling cards, and directories, including all listings in telephone directories;

(3) Any advertisement for prescription drugs shall be made in three commonly prescribed quantities;

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(4) Any advertisement for prescription drugs or prices shall be truthful, reasonable, fully informative, and understandable to the public and shall not be false or misleading;

(5) Any advertisement for prescription drugs shall state the time period during which the prices advertised will be effective; and

(b) The price for prescription drugs advertised shall not be below cost as defined in section 481-3, HRS, as amended.

(c) A pharmacist or the pharmacist's agent upon request however communicated to the pharmacist shall give the current price for any drug sold at the pharmacist's pharmacy for informational purposes only and the price quoted shall not be false or misleading but must be truthful, reasonable, informative, and understandable to the public. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §§461-1, 461-4.5, 461-21) (Imp: HRS §§461-4.5, 461-21)

Historical note: The substance of this section is substantially identical to sections 16-95-5, 16-95-6 and 16-95-7. [Eff 5/16/64; 9/1/74; am 2/3/78; am and ren §§16-95-5, 16-95-6, 16-95-7, 6/22/81; R 12/24/92]

§16-95-102 Procedures to advertise related pharmacy services. Advertising of related pharmacy services is to provide the public with information in a manner consistent with public health and safety and shall be truthful, reasonable, fully informative, and understandable to the public and shall not be false or misleading. A pharmacy may advertise that it performs the following services:

(1) Personal medication record. To qualify as providing this service, a system must be maintained which enables the immediate retrieval of information concerning individual pharmacy patients which is of sufficient scope to enable a determination

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by the pharmacist of rational drug utilization. In accomplishing this purpose the design and use of the system must be to ascertain and record all patient information necessary to assist the pharmacist in avoiding adverse drug reactions, drug-drug interactions, and inappropriate use of drugs.

(2) Professional consultation with patient and practitioners. The availability of patient consultation means that the pharmacist routinely informs the patient, either directly or indirectly, on what the patient is taking, how to take it, what to expect, what special precautions should be observed, and how the medication is to be properly stored. This service is to assure that the patient understands the proper use of the drug and that the practitioner's intentions will materialize in a drug regimen of optimal effectiveness, safety, and duration. Practitioner consultation denotes the availability and practice of pharmacists acting as drug information specialists who discuss with practitioners drug effects interactions, side effects, and drugs of choice for diseased conditions.

(3) "Emergency prescription service" means the providing of pharmaceutical services, which includes prescription dispensing, at any time after usual pharmacy hours. This means that a pharmacist is available, can be readily contacted, and will respond with reasonable expediency at any hour, day or night, in a manner consistent with security and personal safety.

Should the pharmacy choose to advertise the performance of the foregoing services, it shall conform with the definition of that service as herein set forth. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-1, 461-4.5, 461-21)

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Historical note: The substance of this section is based substantially on section 16-95-5. [Eff 5/16/64; am 2/3/78; am and ren §16-95-5, 6/22/81; R 12/24/92]

§16-95-103 Advertising of controlled substances prohibited. No person shall advertise or promote to the public in any manner the sale of a Scheduled II, III, IV, or V controlled substance as defined in the Federal Controlled Substances Act and the rules promulgated thereunder as well as any other controlled substances as defined in chapter 329, HRS, as amended, and the rules promulgated thereunder by the state department of health. [Eff and comp 12/24/92; comp 12/25/04; comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

Historical note: The substance of this section is substantially identical to section 16-95-8. [Eff 9/1/74; am 2/3/78; am and ren §16-95-8, 6/22/81; R 12/24/92]

SUBCHAPTER 13

DISCIPLINARY SANCTIONS, APPLICATION DENIAL, HEARINGS, ADMINISTRATIVE PRACTICE AND PROCEDURE

§16-95-110 Grounds for revocation, suspension, refusal to renew or restore, denial, or conditioning of license or permit. (a) In addition to any other acts or conditions provided by law, the board may revoke, suspend, refuse to renew or restore, deny, or condition a license or permit for any one or more of the following acts or omissions:

(1) Procuring a license or permit through misrepresentation or deceit;

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(2) Failing to meet or maintain the requirements or conditions necessary to qualify for license or permit;
(3) Conviction of, or pleading nolo contendere to a crime that is substantially related to the qualification, functions, or duties of a pharmacist;
(4) Committing any act or omission in the practice of pharmacy or wholesale distribution which constitutes dishonesty, fraud, or misrepresentation with the intent to substantially benefit the pharmacist or wholesale distributor or with the intent to substantially injure another person;
(5) Aiding or abetting an unlicensed person to directly or indirectly evade chapter 461, HRS, or this chapter;
(6) Failing to maintain records or to make accessible any records as required in subchapter 11;
(7) Violating any provisions of the department of health or department of public safety;
(8) Except as provided by law, accepting returns or exchanges of prescription drugs after the drugs have been dispensed;
(9) Dispensing a different drug or brand in place of the drug or brand prescribed without the express consent of the person prescribing;
(10) Failing to comply with the state's drug formulary or substitution laws as set forth in part VI of chapter 328, HRS;
(11) Professional misconduct, gross carelessness, or manifest incapacity;
(12) Violation of any state or federal law, including violation of a drug, controlled substance, or poison law;
(13) False, fraudulent, or deceptive advertising;
(14) Making a false statement on any document submitted or required to be filed by this chapter;

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(15) Habitual intemperance or addiction to the use of habit-forming drugs;
(16) Violating the provisions of chapter 461, HRS, this chapter, or any order of the board;
(17) Failure to comply with the pharmaceutical compounding requirements found in chapters 795 (nonsterile preparations) and 797 (sterile preparations) of the United States Pharmacopeia National Formulary, as amended;
(18) Failure to report, in writing to the licensing authority, any disciplinary decision issued against the licensee or the applicant in another jurisdiction within thirty days of the disciplinary decision.

(b) The board may make recommendations regarding quality improvements to prevent or minimize errors. The board may also fine or impose conditions or limitations upon a license or permit. A hearing on that fine, condition, or limitation may be conducted in accordance with chapter 91, HRS. The violation of any condition or limitation on a license or permit may be cause to impose additional sanctions against the licensee or permittee. Any fine imposed by the board after a hearing in accordance with chapter 91, HRS, shall be no less than $100 and no more than $1,000 for each violation, and each day of violation may be deemed a separate violation. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-17, 461-21, 461-22)

§16-95-111 Denial. In the event an application for the issuance of a license or permit or for the reinstatement thereof is denied, the board shall notify the applicant by letter of the board's action which shall include a concise statement of the reasons therefor and a statement informing the applicant of the applicant's right to a hearing if the applicant so desires. [Eff and comp 12/24/92; comp 12/25/04; comp

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06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-8, 461-14, 461-21, 461-22)

Historical note: The substance of this section is substantially identical to section 16-95-27. [Eff 5/16/64; am and ren §16-95-27; 6/22/81; R 12/24/92]

§16-95-112 Demand for hearing; proceedings upon demand for hearing. (a) Any person whose application for a license or permit or whose application for the reinstatement of a license or permit has been denied by the board shall be entitled to a hearing, provided that a demand for a hearing is filed with the board within sixty days of the date of denial of the application.

(b) If a demand for hearing is filed within the time prescribed, the board shall order a hearing in accordance with chapter 91, HRS, relating to contested cases and unless the context otherwise requires, the rules set forth in chapter 16-201, the rules of practice and procedure of the department. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§91-9, 91-9.5, 91-10, 91-11, 91-12, 461-4.5, 461-21)

Historical note: The substance of this section is substantially identical to sections 16-95-28 and 16-95-29. [Eff 5/16/64; am and ren §§16-95-28, 16-95-29, 6/22/81; R 12/24/92]

§16-95-113 Administrative practice and procedure. The rules of practice and procedure for pharmacies and pharmacists shall be as provided in chapter 16-201, the rules of practice and procedure of the department as adopted, and as may subsequently be amended, which are incorporated by reference and made a part of this chapter. [Eff and comp 12/24/92; comp

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12/25/04; comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§91-2, 461-4.5)

SUBCHAPTER 14

ORAL TESTIMONY

§16-95-118 Oral testimony. (a) The board shall accept oral testimony on any item which is on the agenda, provided that the testimony shall be subject to the following conditions:

(1) Each person seeking to present oral testimony is requested to notify the board not later than forty-eight hours before the meeting, and at that time to state the item on which testimony is to be presented;

(2) The board may request that any person providing oral testimony submit the remarks, or a summary of the remarks, in writing to the board;

(3) The board may rearrange the items on the agenda for the purpose of providing for the most efficient and convenient presentation of oral testimony;

(4) Persons presenting oral testimony at the beginning of the testimony shall identify themselves and the organization, if any, that they represent;

(5) The board may limit oral testimony to a specified time period but in no case shall the period be less than five minutes, and the person testifying shall be informed prior to the commencement of the testimony of the time constraints to be imposed; and

(6) The board may refuse to hear any testimony which is irrelevant, immaterial, or unduly repetitious to the agenda item on which it is presented.

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(b) Nothing in this section shall require the board to hear or receive any oral or documentary evidence from a person on any matter which is the subject of another proceeding pending subject to the hearings relief, declaratory relief, or rule relief provisions of chapter 16-201.

(c) Nothing in this section shall prevent the board from soliciting oral remarks from persons present at the meeting or from inviting persons to make presentations to the board on any particular matter on the board's agenda. [Eff and comp 12/24/92; comp 12/25/04; comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§92-3, 461-4.5)

SUBCHAPTER 15

FEES

§16-95-123 Fees established. The fees are as established in chapter 16-53. The fees for wholesale prescription drug distributors license shall be the same fees as established for a pharmacy in chapter 16-53. [Eff and comp 12/24/92; comp 12/25/04; comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 26-9)

§16-95-124 Form of fee. The fees, if in the form of a money order or check, shall be made payable to the department. [Eff and comp 12/24/92; comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

§16-95-125 Dishonored checks considered failure to meet requirements. The dishonoring of any check upon

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first deposit shall be considered a failure to meet requirements. [Eff and comp 12/24/92; comp 12/25/04; comp 06/22/15; comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

SUBCHAPTER 16

EMERGENCY CONTRACEPTION COLLABORATIVE AGREEMENT

§16-95-130 Emergency contraception written collaborative agreement. (a) Each arrangement between a licensed pharmacist and a licensed physician relating to the distribution to a patient of emergency contraception drugs shall be documented in a signed collaborative agreement in accordance with the form attached hereto as Exhibit A entitled "Emergency Contraception Drug Therapy Collaborative Agreement" dated December 2004, located at the end of this chapter and made a part of this chapter. The agreement shall be delivered to the board by the licensed pharmacist within ten days of the execution of the agreement by the pharmacist and the physician.

(b) Before a pharmacist may participate in the collaborative agreement, the pharmacist shall have completed an emergency contraception training course approved by the ACPE, curriculum-based programs from an ACPE-accredited college of pharmacy, applicable state or local health department programs, or programs recognized by the board of pharmacy. Training shall include procedures listed in Exhibit A, entitled, "Emergency Contraception Drug Therapy Collaborative Agreement", dated December 2004 and located at the end of this chapter, the management of the sensitive communications often encountered in emergency contraception, providing service to minors, quality assurance, referral for additional services, and documentation.

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(c) By executing the collaborative agreement, both the physician and pharmacist agree and acknowledge that:

(1) They accept the responsibility for the distribution of the emergency contraception drugs and that the licensed pharmacist shall dispense only certain drugs approved for emergency contraception by the United States Food and Drug Administration. Some of the currently approved drugs are listed in the attached Exhibit B entitled "Brands and Doses", dated August 2004, located at the end of this chapter and made a part of this chapter however, drugs approved for emergency contraception are not limited to this list. Other drugs listed in Exhibit B entitled "Brands and Doses", dated August 2004 and located at the end of this chapter, may be dispensed instead of Plan B® in the following circumstances:

(A) Plan B® is unavailable;

(B) Plan B® is not covered under the patient's health insurance plan and another drug listed in Exhibit B is covered; or

(C) The patient chooses another listed drug after the pharmacist advises the patient that side effects are usually less with Plan B®.

The list of approved drugs in Exhibit B also shall include adjunctive drugs for treatment of nausea and vomiting that may be associated with emergency contraceptives;

(2) The licensed pharmacist shall provide the patient with drug information concerning dosage, potential adverse side effects, and follow-up contraceptive care;

(3) The collaborative agreement shall be effective for a period of at least two years from the date of its delivery to the board, unless rescinded in writing by either the

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physician or the pharmacist, with written notice to the other and the board, or unless the pharmacy board invalidates the agreement or changes the terms of the agreement. After the two year period, the agreement shall continue to be valid from month to month unless rescinded, invalidated, or changed as provided herein. The licensed pharmacist or the licensed physician, who rescinds the agreement, shall notify the board within three business days of the rescission. At the time the collaborative agreement is rescinded, the licensed pharmacist shall not have prescriptive authority to dispense emergency contraceptives until another collaborative agreement with a physician is completed and received by the board; and

(4) Each drug therapy prescription authorized by the physician and dispensed by the pharmacist shall be documented in a patient profile.

(d) Additionally, the collaborative agreement between the licensed pharmacist and licensed physician shall include:

(1) The name, address, and phone number of the licensed pharmacist and pharmacy and the signature of the licensed pharmacist;

(2) The name, address, and phone number of the licensed physician and the signature of the licensed physician;

(3) The purpose of the collaborative agreement, which is to permit emergency contraception drug therapy within one hundred twenty hours of the patient having unprotected sexual contact and to ensure that the patient receives appropriate information from the licensed pharmacist regarding the drug therapy;

(4) The procedures, delineated in Exhibit A, to be followed by the licensed pharmacist when

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the patient requests drug therapy, including any applicable referrals;

(5) Any limitation agreed upon by both the licensed pharmacist and the licensed physician including but not limited to approved drugs that may not be prescribed to the patient or whether the licensed pharmacist's or the licensed physician's decision shall control in the event of a disagreement on the prescription for a patient;

(6) A provision that the licensed pharmacist shall refer the patient to a licensed physician;

(7) A statement that the label placed on the drug therapy product shall contain the names of both the pharmacist and the physician signers of this agreement;

(8) An informed consent, included in Exhibit A, to be used by the licensed pharmacist to inform the patient about the emergency contraception drug therapy. The informed consent shall be signed by both the licensed pharmacist and the patient; and

(9) A screening checklist for emergency contraception pills, included in Exhibit A, to be filled in by the patient and signed by both the licensed pharmacist and the patient.

(e) Any modification to an existing collaborative agreement previously delivered to the board shall be submitted to the board by the licensed pharmacist at least ten working days prior to the intended implementation of the changed collaborative agreement.

(f) The board shall have the authority to reject a collaborative agreement if the board determines that the collaborative agreement is not in compliance with this section or is not in the best interests of the patient.

(g) The form of the collaborative agreement, the informed consent form, and the screening checklist for

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emergency contraception drugs attached as Exhibit A hereto, shall be made available by the board to licensed pharmacists and licensed physicians." [Eff and comp 12/25/04; am and comp 06/22/15; am and comp 8/15/16] (Auth: HRS §461-4.5) (Imp: HRS §461-1)

SUBCHAPTER 17

Dispensing of Refills During a State of Emergency without a Practitioner's Authorization

§16-95-131 Procedure to dispense a refill without practitioner authorization (a) During a declared state of emergency, a registered pharmacist may dispense and refill to persons directly impacted by the emergency up to a thirty day supply without the practitioners authorization provided that requirements provided in HRS §461-11.9 are met;

(b) Registered pharmacists will use their professional judgment to evaluate the impact of an emergency on a person by taking factors under consideration which include:

(1) The person proximity to emergency.

(2) The person's registered practitioners' proximity to emergency.

(3) Potential effects of emergency and how they will impact a person's healthcare plan and availability.

Subchapter 18

Prescription Drug Label Information Accessibility

§16-95-132 Drug label accessibility (a) Drug label information must be made available to individuals with difficulty seeing or reading.

b) Prescriptions drug containers may include an electronic label which allow individuals to access prescription information through an external accessible device or drug label reader. (do we need to specify where?)

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1. Pharmacies may utilize patient counseling to supplement drug label information accessibility.
   a) Patient counseling will not replace the requirement for pharmacies to provide an external accessible device or drug label reader.

d) Pharmacies shall have an external accessible device or drug label reader readily available to individuals.

§16-95-133 Drug label accessibility exemption (a) Pharmacies applying for an exemption to section 461-13.5, HRS, can do so by submitting a written request to the Board.

a) The Board will grant or deny the request at a meeting that is open to the public and properly notice.
b) The applicant shall hold an active license issued by the Board that is in good standing.
c) The request shall include information that details the current pharmacy staff.
d) An attestation will be included with the request that acknowledges any change in employment related to the pharmacy will be reported to the Board within ten days of the change.
e) An exemption will be immediately forfeit when an exempted pharmacy employs a third pharmacist.

Subchapter 19

Remote Processing

§16-95-134 Remote Prescription Processing
(a) Pharmacists performing remote processing may receive, interpret, evaluate, clarify, and approve medication orders and prescriptions,

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including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V. Remote processing may also include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. Remote processing does not include the dispensing of a drug. To engage in remote processing:

1. The pharmacist must be a Hawaii-licensed pharmacist, unless on the premises of a pharmacy licensed or permitted by the Board.
2. From a pharmacy, the pharmacy must be licensed or permitted by the Board.
3. The pharmacist must have secure electronic access to the pharmacy's patient information system and to other electronic systems that an on-site pharmacist has access to when the pharmacy is open.
4. Each remote entry record must comply with all record keeping requirements for pharmacies, including capturing the positive identification of the pharmacist involved in the remote review and verification of a medication order or prescription.

(b) Remote processing by nationally certified registered pharmacy technicians and pharmacy interns includes nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by a pharmacist is provided using remote supervision. To engage in remote processing:

1. A Hawaii-licensed pharmacist, unless on the premises of a pharmacy licensed or permitted by the Board, remotely supervises the nationally certified pharmacy technician or pharmacy intern via technology that, at a minimum, ensures the pharmacist is (1)

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readily available to answer questions of the nationally certified pharmacy technician or pharmacy intern; and (2) verifies the work performed by the nationally certified pharmacy technician or pharmacy interns.

2. From a pharmacy, the pharmacy must be licensed or permitted by the Board.
3. The **nationally certified** pharmacy technician or pharmacy intern performing remote processing must have secure electronic access to the pharmacy's patient information system and to other electronic systems that an on-site **nationally certified** pharmacy technician or pharmacy intern has access to when the pharmacy is open.
4. Each remote entry record must comply with all record keeping requirements for pharmacies.
5. The nationally certified technician or pharmacy intern must be performing the remote prescription processing from a location within the United States.

2. Material, except source notes and other notes, to be repealed is bracketed and stricken. New material is underscored.

3. Additions to update source notes and other notes to reflect these amendments and compilation are not underscored.

4. These amendments to and compilation of chapter 16-95, Hawaii Administrative Rules, shall take effect ten days after filing with the Office of the Lieutenant Governor.

I certify that the foregoing are copies of the rules, drafted in the Ramseyer format pursuant to the requirements of section 91-4.1, Hawaii Revised

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Statutes, which were adopted on MM DD, YYYY, and filed with the Office of the Lieutenant Governor.

_____
NADINE Y. ANDO
Director of Commerce and
Consumer Affairs

APPROVED AS TO FORM:

_____
Deputy Attorney General

EXHIBIT "A"

This Emergency Contraception Drug Therapy collaborative Agreement was developed using the collaborative agreements of Washington and California, who developed their guidelines from the American College of Obstetricians and Gynecologists and the World Health Organization and physicians, pharmacists and nurses. This Agreement has been approved by the Board of Pharmacy, State of Hawaii.

Emergency Contraception Drug Therapy Collaborative Agreement

As a licensed physician authorized to prescribe medications in the State of Hawaii, I authorize the licensed pharmacist _____ to initiate emergency contraception drug therapy according to the terms and conditions that follows and according to Hawaii Administrative Rule § 16-95-__. This Agreement provides written terms and conditions for initiating emergency contraception drug therapy in accordance with the laws and rules of the State of Hawaii. This agreement shall be delivered to the Department of Commerce and Consumer Affairs within seven (7) days of the execution of the agreement by the licensed pharmacist and the licensed physician. Any modification to an existing collaborative agreement previously delivered to the Department shall be delivered also to the Department by the licensed pharmacist at least ten working days prior to the intended implementation of the changed collaborative agreement.

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Purpose: Permit the use of drug therapy within 120 hours of the patient having unprotected sexual contact and to ensure the patient receives adequate information to successfully complete drug therapy.

Procedures: When the pharmacist's patient requests drug therapy, the pharmacist shall assess the need for drug therapy and/or referral for contraceptive care and reproductive health care. The pharmacist shall determine the following:

1. The date of the patient's last menstrual period to rule out established pregnancy;
2. Whether the elapsed time since unprotected intercourse is less than 120 hours;[1]
3. Whether the patient has been a victim of sexual assault; and
4. That the patient is at least 14 years of age.

Referrals: The licensed pharmacist shall refer the patient to the licensed physician for follow-up. If drug therapy services are not available at the pharmacy, the pharmacist shall refer the patient to another licensed pharmacist. Also, the pharmacist shall refer the patient to see either a medical doctor or family planning clinic provider if:

A. The pharmacist cannot rule out that the patient is pregnant or if the elapsed time since the patient having unprotected intercourse is greater than 120 hours;
B. The pharmacist is concerned that the patient may have been exposed to a sexually transmitted disease;
C. The patient doses not have a regular contraceptive method; and
D. The patient does not have a health care provider and needs free or low cost family planning services.

If the pharmacist is concerned that the patient may have contracted a sexually transmitted disease through unprotected sexual activity and/or if the patient indicates that she has been sexually assaulted, the pharmacist shall initiate referral to a medical doctor, a family planning clinic, a sexual assault treatment center, the police, or multiple referrals to these entities as the pharmacist may deem appropriate, while providing drug therapy. When the patient is a minor and sexual assault or sexual abuse is suspected, the pharmacist shall report or cause a report to be made to the police and Child Protective Services.

While drug therapy can be used repeatedly without serious health risks, patients who request drug therapy shall be referred to a medical doctor or family planning clinic provider for consideration of the use of a regular contraceptive method.

Drug Therapy product selection: The pharmacist shall provide medication from a list of drugs approved for emergency contraception by the United States Food and Drug Administration ("FDA") listed in Exhibit B and agreed upon as part of this collaborative Agreement. Plan B® shall be the preferred drug therapy. The list shall include emergency contraceptives and adjunctive medications for nausea and vomiting associated

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with emergency contraceptives. The list shall be maintained at the pharmacy and shared by all participants in the agreement. Along with the medication, the pharmacist shall provide information concerning dosage, potential adverse effects, and follow-up contraceptive care.

Prescription labeling: The label placed on the drug therapy product shall contain the names of both the pharmacist and the physician signers of this Agreement.

Documentation: Each drug therapy prescription authorized by the physician and initiated by the pharmacist shall be documented in a patient profile.

Training: The pharmacist who participates in the drug therapy must have completed a training program on emergency contraception by an American Council on Pharmaceutical Education (ACPE) approved provider. Training must include procedures listed above, the management of the sensitive communications often encountered in emergency contraception, service to minors, quality assurance, referral for additional services, documentation and a crisis plan if the pharmacy operations are disrupted by individuals opposing the emergency contraception.

Further, the pharmacist agrees to participate in the Emergency Contraception Hotline.

Term of the Agreement: This agreement shall be effective for a period of at least two years from the date its delivery to the Department unless rescinded in writing earlier by either the physician or the pharmacist, with written notice to the other and to the Department, or unless the Pharmacy Board invalidates such Agreement or changes the terms of the agreement. After the two year period, the agreement shall continue to be valid month to month unless rescinded, invalidated, or changed as provided herein. The licensed pharmacist or the licensed physician, who rescinds the agreement, shall notify the Department within three business days of the rescission. At the time the collaborative agreement is rescinded, the licensed pharmacist shall not have prescriptive authority to dispense emergency contraceptives until another collaborative agreement with a physician is completed and delivered to the department.

Additional Terms or Limitations:

_____

_____

_____

_____

_____

_____

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Physician's Name: _____

Street Address/City/State; Zip Code:
_____

Phone Number: _____ MD License No.: _____

Physician's Signature: _____ Date:
_____

Pharmacist Name: _____

Street Address/City/State/Zip Code where Drug Therapy will occur (include name of pharmacy, pharmacy license number, pharmacist-in-charge and pharmacist-in-charge license number):

_____ Pharmacist License No.: _____

_____

_____

_____

Phone Number: _____

Pharmacist's Signature: _____ Date:
_____

Pharmacist-in-charge's Signature: _____ Date:
_____

(Name of Pharmacy)

Informed Consent for Emergency Contraception Drug Therapy

Name of Patient: _____ Age:
_____

Address: _____

Phone No.: _____

First day of last menstrual period: ___/___/_____
Mo/Day/Year

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Date of unprotected sexual intercourse: ___/___/____
Mo/Day/Year

If more than one exposure, give date and time of initial exposure:
_____

Was this sexual intercourse the result of sexual assault? Yes ___ No ___

Before giving your consent, be sure that you understand both the pros and cons of Emergency Contraceptive Pills (ECPs). If you have any questions, we will be happy to discuss them with you. Do not sign your name at the end of this form until you have read and understood each statement and the pharmacist has answered your questions and can witness your signature. This information is confidential.

I understand that:

1. ECPs contain hormones that act to prevent pregnancy. These pills are taken after having unprotected sex (sex without birth control or birth control failure). They are to be used as an emergency treatment only and not as a routine method of contraception.
2. ECPs work by preventing or delaying the release of an egg from the ovary, preventing fertilization, or causing changes in the lining of the uterus that may prevent implantation of a fertilized egg. I understand that if I am already pregnant, ECPs will not stop or interfere with the pregnancy.
3. ECP treatment should be started within 5 days (120 hours) of unprotected sex.
4. ECPs are not 100 percent effective.
5. Reactions to the pills may include: nausea and vomiting, fatigue, dizziness, breast tenderness, early or late menstrual period.
6. I should see a physician if my period has not started within 3 weeks after treatment.
7. I should use condoms, spermicides, or a diaphragm, or continue taking birth control pills to prevent pregnancy if I have sex before my next period. After that, I should continue to use a method of contraception.
8. ECPs will not protect me from or treat sexually transmitted diseases and I should seek diagnosis and treatment if I am concerned because I have had sex with a new partner in the past month or my partner has had sex with someone else in the past month or my partner has a sexually transmitted disease.
9. I understand that it maybe useful to share this treatment information with my regular health care provider. Therefore, I request and authorize the release of this information to the following designated provider:
   Yes ___ No ___
10. Designated Provider's Name: _____

Patient's Signature: _____ Date: _____

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Informed Consent for Emergency Contraception Drug Therapy Continued

Pharmacist's Signature: _____Date: _____

Pharmacist only: Referral made to: _____

Rx No.: _____

Screening Checklist for Emergency Contraceptive Pills

Patient Name: _____ Today's Date: _____

Address: _____ Age: _____

_____

These questions are to help us understand what you need right now.

1. Have you had unprotected sex during the last 5 days? Yes ___ No ___

2. On what day(s) did you have unprotected sex in the past 5 days?

Monday ___ Tuesday ___ Wednesday ___Thursday ___Friday ___ Saturday ___ Sunday ___

3. What time of day was the first unprotected sex in the past 5 days? _____ A.M. _____ P.M.

4. Have you had unprotected sex prior to the last five days? Yes ___ No ___

5. When was the first day of your last menstrual period? Date: _____

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6. Are you currently using a method of birth control?

No method ___ Birth Control Pills ___
Condoms ____ Diaphragm _____
IUD _____ Other Method _____
Contraceptive Shot (Depo Provera®) ___

7. Did you have unprotected sex as a result of sexual assault (or, did anyone pressure you into having sex when you didn't want to?)

Yes ___ No ___

8. Would you like a pharmacist to call you in the next couple of weeks to see how you're doing?

Yes ___ No ___

If yes, what time of the day is best to call? _____ A.M. _____ P.M.

Patient's Signature: _____Date: _____

For Pharmacist Use Only

Date and time of interview: _____ EC Provided: Yes ___ No ___

Referral made for (check all that apply):

Contraception follow-up ___ Evaluation for STD ___ Other medical evaluation ___
Pregnancy counseling _____ Assault Counseling ___ No referrals made _____

Date and time of callback: _____ Referrals made then? _____

Pharmacist's Signature: _____Date: _____

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EXHIBIT "B"

Brands and Doses

Of Oral Contraceptive Pills Used For Emergency Contraception

There are now two prepackaged emergency contraceptive pill products (dedicated emergency contraceptive pills) as well as 14 brands of birth control pills that can be used for emergency contraception.

Brand	Manufacturer	Pills per Dose (Treatment schedule is one dose ASAP after unprotected intercourse, and a second dose 12 hours later)	Ethinyl Estradiol per Dose (mcg)	Levonorgestrel per Dose (mg)*
Dedicated Emergency Contraceptive Pills				
Plan B	Women's Capital Corporation	1 white pill	0	0.75
Preven	Gynetics	2 blue pills	100	0.50

Oral Contraceptive Pills				
Levora	Watson	4 white pills	120	0.60
Levlen	Berlex	4 light-orange pills	120	0.60
Lo/Ovral	Wyeth-Ayerst	4 white pills	120	0.60*
Low-Ogestrel	Watson	4 white pills	120	0.60*
Nordette	Wyeth-Ayerst	4 light-orange pills	120	0.60
Alesse	Wyeth-Ayerst	5 pink pills	100	0.50
Aviane	Duramed	5 orange pills	100	0.50
Levlite	Berlex	5 pink pills	100	0.50
Ogestrel	Watson	2 white pills	100	0.50*
Ovral	Wyeth-Ayerst	2 white pills	100	0.50*
Tri-Levlen	Berlex	4 yellow pills	120	0.50
Triphasil	Wyeth-Ayerst	4 yellow pills	120	0.50
Trivora	Watson	4 pink pills	120	0.50

Adapted from RA Hatcher, et al, *Contraceptive Technology: Seventeenth Revised Edition*. New York NY: Ardent Media, 1998. Updated by Felicia Steward, MD 2001.

*** This progestin in Ovral, Lo/Ovral, Low-Ogestrel, Ogestrel and Ovrette is norgestrel, which contains two isomers only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.**

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Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine, Bonine)	One or two 25mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours.

Dimenhydrinate (Dramamine)	One or two 50mg tablets or 4-8 teaspoons liquid	30 minutes to l hour before first ECP dose; repeat as needed every 4-6 hours.
Cyclizine hydrochloride (Marezine)	One 50mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours.

Adapted from RA Hatcher, et al, *Contraceptive Technology: Seventeenth Revised Edition*. New York NY: Ardent Media, 1998. Updated by Felicia Steward, MD 2001.

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